CLINICAL STUDY PROTOCOL

This protocol has regard for the HRA guidance.

FULL STUDY TITLE: Hand And Wrist: Antimicrobials and Infection – burieD vs. exposed K-wiRes In Fracture fixaTion (HAWAII-DRIFT)

SHORT STUDY TITLE: Buried vs exposed wires in hand and wrist fractures

STUDY ACRONYM: HAWAII-DRIFT

Version: 2.0 11Mar2026

Study website: https://hawaii.octru.ox.ac.uk

Contents

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2 ORGANISATIONAL INFORMATION

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Sponsor:	University of Oxford Refer to the KEY STUDY CONTACTS section for contact details.
CTU:	The study is coordinated by Oxford Trauma and Emergency Care, part of the following UK Clinical Research Collaboration registered CTU: Oxford Clinical Trials Research Unit (OCTRU) Botnar Research Centre, University of Oxford, Windmill Road, Headington, Oxford, OX3 7LF.
Funder:	National Institute for Health and Care Research (NIHR).
Co-applicants on the study grant:	The following are co-applicants on the study grant and have contributed to the study design and development of the protocol: **Mr. Matthew Gardiner (Co-CI)** Consultant Hand and Plastic Surgeon Frimley Health NHS Foundation Trust ✉ matthew.gardiner@nhs.net **Prof. Jonathan Cook** Professor of Medical Statistics ✉ jonathan.cook@ndorms.ox.ac.uk **Dr. Juul Achten** Research Manager ✉ juul.achten@ndorms.ox.ac.uk **Dr. Duncan Appelbe** Senior Information Specialist ✉ duncan.appelbe@ndorms.ox.ac.uk **Dr. May Ee Png** Senior Researcher in Health Economics ✉ may.png@phc.ox.ac.uk

	Prof. Matthew Costa Professor of Orthopaedic Trauma ✉ matthew.costa@ndorms.ox.ac.uk **PATIENT AND PUBLIC CONTRIBUTORS** **Mr Joey Isaacs** Patient and Public Involvement (PPI) Representative
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Conflict of Interest statement:	None of the co-applicants/protocol contributors listed above have declared a potential conflict of interest.
Confidentiality:	In accordance with NIHR Open Access policy, the protocol will be published and made freely and openly accessible to all.

3 KEY STUDY CONTACTS

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4 PROTOCOL APPROVAL/SIGNATORIES

This protocol has been approved by the Sponsor, Chief Investigator (CI) and Lead Study Statistician. Approval of the protocol is documented in accordance with OCTRU Standard Operating Procedures (SOPs).

All parties confirm that findings of the study will be made publicly available through publication without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any important deviations and serious breaches of Good Clinical Practice (GCP) from the study as planned in this protocol will be explained.

5 LAY SUMMARY/PLAIN ENGLISH SUMMARY

Broken bones in the hand and wrist are very common in the UK. They usually happen at work, following a fall or during sports. Sometimes, when these bones are broken, surgery will be needed to fix them. This is usually the case if the bones have broken and fallen out of place. Fixing broken bones in the hand and wrist is routinely performed in the National Health Service (NHS), accounting for about half of all surgeries for hand and wrist injuries.

During the surgery, the doctors will move the bones back into the right place and then use metal wires to hold them. These wires fix the bones in place while they heal. Once the bones have healed, the wires are then removed.

When the wires are put in, the ends of the wires can either stick out of the skin or be buried under the skin. There are no reliable studies that tell us if one option is better for patients.

Both options have advantages and disadvantages. Wires buried under the skin might lower the risk of the hand or wrist becoming infected. This option is more expensive for the NHS and requires another surgery to remove the wire. Wires sticking out of the skin make them easy to remove and are cheaper for the NHS, however, patients might have a higher chance of getting an infection. This is important, as infections after surgery can be very serious. Infections can mean people need to come back into hospital for antibiotics and possibly further surgeries. It can also mean that their hands and wrists will recover slower, affecting work and daily life.

This is a study to compare the two options to work out which is better. Participants with broken bones in the hand or wrist that need fixing with metal wires will be randomly chosen to have their wires buried or left sticking out. By choosing randomly, the two groups will be equal, except for whether the wire end is buried or left sticking out. The number of infections will be checked after 90 days and 6 months, and hand and wrist recovery will be checked at 6 months.

This study will be run in at least 22 hospitals around the UK, to make sure the results represent the whole country. Results from this study will help us decide how best to treat patients with broken hand and wrist bones that need surgery.

6 STUDY SYNOPSIS

Full Study Title:	Hand And Wrist: Antimicrobials and Infection – burieD vs. exposed K-wiRes In Fracture fixaTion (HAWAII-DRIFT)	
Short Title:	Buried vs exposed wires in hand and wrist fractures	
Study Design:	Multi-centre, two arm, parallel design, superiority, randomised controlled clinical study.	
Study Aim/Primary Objective:	To compare the risk of Surgical Site Infection (SSI) by 90 days post-randomisation between buried and exposed Kirschner wires (K-wires) in patients treated for hand and wrist fractures	
Study Participants/ Target Population:	Adults aged 16 years and over with fractures of the hand or wrist who require fixation with K-wires.	
No. of study groups:	Two	
Intervention A:	Buried K-wires	
Intervention B:	Exposed K-wires	
Planned Sample Size:	470 participants	
Target no. of research sites:	At least 22 research sites	
Countries of recruitment:	UK	
Planned study period	01/01/2026 – 28/02/2028	
Planned recruitment duration:	01/01/2026 – 28/02/2027	
Duration of intervention:	K-wires will usually remain in place for 3 to 6 weeks	
Follow-up duration:	Each participant will be followed up for 6 months from randomisation.	
Primary objective and outcome measure:	**Objective** To compare the risk of SSI by 90 days post-randomisation between buried and exposed K-wires in patients treated for hand and wrist fractures	**Outcome Measure** *Site reported* Presence of SSI requiring treatment with systemic antibiotics (oral, intravenous or topical) up to 90 days post-randomisation.

		Participant reported Participant reported treatment with systemic antibiotics (oral, intravenous or topical) received for a wound infection at the site of their fracture fixation.
Additional objectives and outcome measures:	Refer to the OBJECTIVES AND OUTCOME MEASURES section of the main body of the protocol for full study objectives and outcome measures.	

7 ABBREVIATIONS

AE	Adverse Event
CI	Chief Investigator
CRF	Case Report Form
CTU	Clinical Trials Unit
DMP	Data Management Plan
ED	Emergency department
GCP	Good Clinical Practice
GP	General Practitioner
HRA	Health Research Authority
ICF	Informed Consent Form
eISF	Electronic Investigator Site File
ISRCTN	International Standard Randomised Controlled Trials Number
K-wire	Kirschner wire
NDORMS	Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health and Care Research
OCTRU	Oxford Clinical Trials Research Unit
PI	Principal Investigator
PIS	Participant information sheet
PPI	Patient and Public Involvement
PROMIS	Patient-Reported Outcomes Measurement Information System
QA	Quality Assurance
QALY	Quality Adjusted Life Year
REC	Research Ethics Committee
REDCap	Research Electronic Data Capture
RGEA	Research Governance, Ethics & Assurance
SAE	Serious Adverse Event
SAP	Statistical Analysis Plan
SOP	Standard Operating Procedure
SSI	Surgical Site Infection
eTMF	Electronic Trial Master File
TMG	Trial Management Group
VAS	Visual Analogue Scale

8 BACKGROUND INFORMATION AND RATIONALE

8.1 Background

Due to the central role of the hand and wrist in our everyday lives, injury through occupation, recreation, accidents and altercations is common (1). Hand and wrist trauma can have a substantial impact on an individual's ability to look after themselves and earn a living (2, 3). These injuries are increasing in the UK and across all healthcare settings globally (4, 5). Data from NHS England revealed that in 2015/2016 there were 4.58 million patients who presented to the Emergency Department (ED) with hand trauma (6).

Fractures of the bones of the hand and wrist are the most common subtype of hand trauma, accounting for about 50% of all injuries (5). Although most do not need surgery, a proportion will be unstable and will require manipulation and fixation with metalwork to restore hand function (7, 8). Recent UK studies indicate that over 50,000 hand and wrist fractures are operated on per year in the NHS (5, 9). If a hand or wrist fracture requires fixation, then K-wires are usually employed to stabilise the bone following manipulation and reduction of the fracture.

Once a fracture has been fixed with K-wires, the wires are routinely removed when the bone has healed. When the wires are placed, the ends of the wires may be cut short and buried beneath the skin, or the end of the wires can be left exposed outside of the skin. There is currently no reliable data to inform practice, nor any health economic data to inform national guidelines.

Based on our national clinician survey, the key rationale for burying the end of the wire is the perceived reduction in risk of infection (10). The interface between an exposed wire and the skin is a site of potential Surgical Site Infection (SSI), commonly referred to as a 'pin site infection'. Pin site infections are superficial SSIs that usually require treatment with antibiotics, with or without removal of the wire. A major concern is deep SSI, where the bone and/or joint becomes infected due to bacterial transport along the wire and into the bone in which it is placed. The baseline risk of SSI following K-wire fixation is 7.0% [CI 4.7 to 10.4] based on meta-analysis of 43 studies of 5,739 patients (11).

For patients, the consequences of SSI following hand and wrist trauma surgery include worse and prolonged pain, continued antibiotic prescription, re-operation, hospital admission, delayed rehabilitation and in severe cases, amputation of all or part of the affected hand (17–20). Acquiring an SSI doubles the length of hospital stay and leads to substantial additional direct healthcare costs of up to £6,626 per patient (12, 13).

There have been several studies attempting to evaluate the difference in SSI risk between buried and exposed wires in hand and wrist fractures. We performed a systematic review of buried versus exposed K-wires in all upper limb fractures, identifying nine studies; there was an SSI risk of 13.5% in exposed wires (n=397) versus 6.1% in buried wires (n=525) (23). Only one study was randomised, evaluating 56 patients with distal radius fractures, with a 34.5% SSI risk in the exposed group (n=29) compared to a 7.4% risk in the buried group (n=27) (14). This trial was deemed to be at high risk of bias due to archaic randomisation technique (sealed paper envelopes) and minimal detail of methodology in the study report, including missing data, outcome assessment and loss to follow-up. This study was unblinded, but due to the nature of the intervention, blinding the participant and surgeon is not practical. The other 8 studies in our review were small, mostly retrospective, non-randomised observational comparisons of the two techniques and were at high risk of bias due to confounding, missing data, unclear outcome assessment and loss to follow-up (15). Since our review, another systematic review of 11 studies including 2,022 participants with hand, wrist and forearm fractures has found a risk of 14.5% in exposed K-wires (n=1,048), with a 5.6% risk for buried K-wires

(n=984) (16). Again, the included studies were at high risk of bias, with flaws in the meta-analysis methodology and no health economic analysis.

9 OBJECTIVES AND OUTCOME MEASURES

9.1 Aim

To conduct a randomised controlled trial to evaluate the clinical and cost effectiveness of burying K-wires compared to leaving them exposed following fixation of adult hand or wrist fractures in terms of reducing SSI.

9.2 Primary objective and outcome measure

The primary objective and outcome measure are defined in Table 1.

Table 1: Details of primary objective

Objective	Outcome measure	Time point(s) of evaluation of this outcome measure (if applicable)	Data required	Source data
To compare the risk of SSI by 90 days post-randomisation between treatment groups	Site reported non-validated Case Report Form (CRF) Participant reported non-validated CRF	90 days	Presence of SSI requiring systemic antibiotics (oral, intravenous or topical) up to 90 days post randomisation.	Hospital records Participant questionnaire

SSI: There is no consensus on the classification system to define an SSI. In the context of antimicrobial stewardship and resistance, it has been decided that– treatment with antibiotics - is a suitable surrogate for diagnosis of SSI.

Hospital records for all participants will be reviewed by appropriately trained staff for indicators of infection at 90 days and 6 months post-randomisation. In addition, at 90 days and 6 months post-randomisation, the participants will self-report on potential infections that required treatment with systemic antibiotics (oral, intravenous, or topical).

9.3 Secondary objectives and outcome measures

The secondary objective/s and outcome measure are defined in Table 2.

Table 2: Details of secondary objectives

Objective	Outcome measure	Time point(s) of evaluation of this outcome measure (if applicable)	Data required	Source data (including location)
To compare upper extremity function and pain between treatment groups	Patient-Reported Outcomes Measurement Information System (PROMIS Upper Extremity)	Pre-injury baseline, post-injury baseline, 90 days and 6 months	PROM scores (PROMIS Upper Extremity)	Participant questionnaire
To compare Health-Related Quality of Life between treatment groups	EQ-5D-5L	Pre-injury baseline, post-injury baseline, 90 days and 6 months	PROM scores (EQ-5D-5L)	Participant questionnaire
To compare the risk of complications between groups	Site reported Complications CRF including specifically secondary procedures for SSI (e.g. removal of k-wire for infection, debridement etc.)	Post-surgery treatment proforma, 6 months	Further surgery for SSI and other surgical complications	Hospital records
To assess costs and comparative cost-effectiveness between treatment groups	Bespoke participant resource use questionnaire	90 days, 6 months	Resource use questionnaire	Participant questionnaire
	EQ-5D-5L	90 days, 6 months	EQ-5D-5L	Participant questionnaire

PROMIS Upper Extremity: PROMIS is a collection of patient-reported health status tools that were developed to be disease non-specific in collaboration with the US National Institute for Health (17). For the purposes of this study, the computer adaptive test "CAT" (average eight questions) will be used. PROMIS Upper Extremity will be collected at baseline (a retrospective pre-injury score and baseline at time of consent), 90 days and 6 months post-randomisation. For participants unable to complete follow-up electronically PROMIS Upper Extremity – Short Form (7a) will be used at the 90 days and 6-month time-points via paper questionnaire.

EQ-5D-5L: The EQ-5D-5L is a validated, general health-related quality of life questionnaire consisting of five dimensions (mobility, self-care, usual activities, pain/discomfort and anxiety/depression) each with five levels, the responses to which will be converted into multi-attribute utility scores using an

established algorithm (18). A second component of the EQ-5D-5L comprises a Visual Analogue Scale (VAS) measuring health from 0 (worst imaginable health state) to 100 (best imaginable health state). The EQ-5D-5L will be collected twice at baseline in line with the PROMIS Upper Extremity. Thereafter, the EQ-5D-5L will be collected at 90 days and 6 months post-randomisation.

Complications: All complications related to the fracture or its treatment will be recorded up to 6 months post-randomisation. The complications of interest include further surgery for SSI, other complications of surgery, and complications of anaesthesia. Please refer to section 22.3 Expected AEs for further details.

Health and social care resource use: Health and social care resource use will be measured in the participant questionnaires for the purposes of the economic evaluation. The cost consequences following discharge, including NHS (including inpatient, outpatient and accident and emergency) and personal social service costs and participants' out-of-pocket expenses and costs associated with lost productivity (being out of work) will be recorded via a short questionnaire at 90 days and 6 months post-randomisation.

9.4 Exploratory objectives/additional mechanistic objectives outcomes

Not applicable for this study.

9.5 Use of core outcome sets

No core outcome set is available for this setting.

10 STUDY DESIGN AND SETTING

The HAWAII-DRIFT study is a multi-centre, two arm, parallel design, superiority, randomised controlled clinical study.

The study will recruit 470 participants (235 in each of the two groups) with hand or wrist fractures. Participants will be randomised to receive buried K-wires or exposed K-wires.

A study flow chart is provided in APPENDIX 1 – STUDY FLOW CHART.

10.1 Research sites/site types

Participants will be recruited from hand trauma clinics and orthopaedic fracture clinics from a minimum of 22 NHS secondary care hospitals who see patients with phalangeal, metacarpal, carpal bone or distal radius fractures.

Refer to section 28 for information on identification and management of research sites.

10.1.1 Participant Identification Centres

Participant Identification Centres are not used in this study.

10.2 Collection of outcome data and follow-up assessments

At 90 days and 6 months post-randomisation participants will receive a personalised link via email/SMS (as per their preference) to an electronic questionnaire including the outcome tools as outlined above. A schedule of email/SMS reminders, with telephone or postal mail out as alternative methods for data collection will be specified in the trials Data Management Plan (DMP). There is no plan to directly contact the participants' General Practitioner (GP) for information regarding non-hospital follow-up. Antibiotic prescription by the GP will be recorded in the participant-reported follow-up questionnaires.

Refer to Appendix 2 for full details of outcome data collection and follow-up assessments.

10.3 Countries of recruitment
UK

10.4 Duration of participant involvement
Participants will be in the study for approximately 6 months from randomisation to last protocol activity.

10.5 Post-study treatment/care and follow-up
Following a participant's initial surgery with the randomised intervention, they will receive standard care.

10.6 Central review procedures
Not applicable for this study.

10.7 Use of clinical registries and national datasets (e.g. NHS England)
No data of this type is to be accessed for this study.

10.8 Expected recruitment rate
A conservative recruitment rate of 2 participants per research site per month has been based on screening and recruitment data collected during our national service evaluation, as well as experience from other trials in hand and wrist trauma (DRAFFT (NIHR-HTA 08/116/97), DRAFFT 2 (NIHR-HTA 15/27/01), DRAFT3-CASP (NIHR134681) and WISE (NIHR205011)). It is anticipated that the overall target of 470 participants can be recruited in 15 months.

10.9 Equality, diversity and inclusion for study participants
Hand and wrist trauma affects a spectrum of people, across all social strata, and therefore diversity and equality in hand trauma trials is paramount.

Hand trauma tends to occur in the young, working population, especially in manual labourers. This is known to be an underserved population in terms of representation in National Institute for Health and Care Research (NIHR) research. Wrist fractures typically have a bimodal distribution, with high energy injuries occurring in younger patients and fragility fractures occurring in the older population. The set-up of hand and wrist trauma services in the UK means that the majority of these injuries will be referred from regional units to tertiary hand units, where participants will be recruited from (6). This widens the geographic and socioeconomic reach of the study, as each research site will serve a diverse population.

Oxford Trauma and Emergency Care have expertise and a strong track record of designing and delivering upper limb trauma trials with equality, diversity and inclusivity at the forefront. This trial will build on knowledge gained from previous wrist fracture trials which have been developed with an understanding of under-served populations in trauma, using the INCLUDE framework and the Trial Forge key questions worksheet.

As trauma centres have large catchment areas, most centres have a diverse population in terms of urban, rural and coastal areas and a range of socioeconomic groups. However, there are higher levels of social deprivation in different regions of the UK, hence we will ensure trauma centres from diverse regions of the UK are involved. The central trial team have collaborated with over 100 hospitals on trauma trials in diverse regions with the UK and have access to heat maps of regional socio-demographics and historical research activity via the supporting local Clinical Research Network, which will aid site recruitment planning.

The central trial team will prepare trial materials in different formats to allow for informed consent discussions to be accessible for a large audience. Written materials will be created in normal and large fonts, information will be available in visual formats such as infographics and explainer videos, with voiceovers and subtitles which can be played at various speeds.

The Index of Multiple Deprivation (IMD) will be collected for all individuals screened in the UK for the study to inform assessment of inclusivity regarding social deprivation. Staff involved in the screening and recruitment of participants will be provided with a link to a web-based IMD Decile Lookup tool (managed by OCTRU) to obtain an individual's IMD decile group. Site staff will record the IMD decile on the screening log within the REDCap data collection system alongside the UK nation where the individual resides to allow the study team to determine which national dataset was used to calculate the IMD score.

10.10 End of study

The end of study is the point at which all the data has been entered/received and all queries resolved.

The Sponsor and the CI reserve the right to terminate the study earlier at any time. In terminating the study, they must ensure that adequate consideration is given to the protection of the participants' best interests.

11 SCREENING AND PARTICIPANT ELIGIBILITY CRITERIA

Participant eligibility will be confirmed by a suitably qualified and experienced individual who has been trained on the study and delegated to do so by the Principal Investigator (PI).

11.1 Overall description of study participants

The HAWAII-DRIFT study will recruit adults aged 16 or over with hand or wrist fractures that require fixation with K-wires.

11.2 Inclusion Criteria

A patient will be eligible for inclusion in this study if **ALL** of the following criteria apply:

- Age 16 years and above
- Open or closed hand/wrist fracture(s) which, in the opinion of the treating clinician, requires manipulation under anaesthetic and fixation with K-wires*

*If a participant has sustained more than one fracture requiring k-wire fixation, all those fractures need to be treated in accordance with the randomisation allocation; bilateral and ipsilateral fractures can be included; it will be up to treating clinician to decide which injury or which hand/wrist (i.e., left or right) will be randomised into the study.

11.3 Exclusion Criteria

A patient will not be eligible for the study if **ANY** of the following apply:

- Insufficient soft tissue cover to bury the wire
- Presence of overlying or adjacent skin infection/disorder
- Injury is more than 2 weeks old at time of screening
- Inability of participants to adhere to the trial procedures and/or follow-up procedures

11.4 Rationale for inclusion and exclusion criteria

These criteria will maximise the external validity of the study. Patients who do not have adequate soft tissue cover are those usually with high energy injuries that require complex soft tissue reconstruction alongside fracture fixation. These patients will be at high risk of wound complications and are not comparable with most patients with hand fractures who need K-wire fixation. Patients with pre-existing infection will not be eligible as infection is the primary outcome.

11.5 Screening tests or investigations

There are no pre-study screening tests for inclusion in the study.

11.6 Timing of eligibility assessment

Eligibility will be assessed upon initial entry into the study, usually in the hand trauma or fracture clinic. A second eligibility assessment will be performed immediately prior to surgery, in theatre, confirming eligibility at the point of randomisation.

11.7 Re-screening if a potential participant does not meet inclusion/exclusion criteria at first assessment

If a potential participant does not meet the inclusion/exclusion criteria at first assessment, they can be re-screened at their pre-operative assessment by the surgical team. For example, a patient with a fracture may be seen at initial presentation and the clinical team may feel that a non-operative approach is preferable. However, if that patient is seen again for another review a week later with a repeat X-ray, as is usual practice, and the decision is changed to an operative approach with K-wire fixation, then they can be re-screened at this point. Equally, if a patient is deemed eligible at first presentation, but later presents for their operation with a skin infection over the intended site of K-wire placement, then they can later be deemed ineligible.

11.8 Use of screening logs

A screening log within the Research Electronic Data Capture (REDCap) data collection system will be used to record information about the number of patients assessed for eligibility and/or approached for the study and if provided, the reasons for exclusion or declined consent. Screening logs will record the date of injury, age, biological sex, deprivation index, and if provided, the reasons for declining participation to determine the number of patients assessed for eligibility and reasons for exclusion. In addition, ethnicity will also be recorded if the patient provides verbal consent.

Screening data will be reviewed monthly by the central study team to assess whether representative samples of patients are being approached and to ensure no selection bias occurs in any of the research sites with approach and inclusion/exclusion of specific groups of patients.

11.9 Duration between screening and randomisation

Participants will need to be screened and consented within two weeks of injury.

11.10 Protocol waivers to entry criteria

Protocol adherence is a fundamental part of the conduct of a research study. There will be no exceptions regarding eligibility (i.e. each participant must satisfy all the eligibility criteria). Changes to the approved inclusion and exclusion criteria may only be made by a substantial amendment to the protocol.

Before randomising a patient onto the study, the PI or designee will confirm eligibility. If unsure whether the potential participant satisfies all the entry criteria and to clarify matters of clinical discretion, investigators should contact the central study team, who will contact the CI or designated clinicians as necessary. If in any doubt, the CI must be consulted before recruiting the patient. Details

of the query and outcome of the decision must be documented in the electronic Investigator Site File (eISF) and electronic Trial Master File (eTMF).

11.11 Clinical queries and protocol clarifications

Every care has been taken in drafting this protocol. Contact the central study team for clarification if any instructions seem ambiguous, contradictory or impractical. Clinical queries must also be directed to the central study team. All clinical queries and clarification requests will be logged, assessed and a written response provided. Minor administrative corrections or clarifications will be communicated to all study investigators for information as necessary. For urgent safety measures or changes that require protocol amendment see section 29.6.

12 RECRUITMENT

A minimum of 22 research sites will be opened to recruitment.

12.1 Participant Identification

The following methods will be used to identify potentially eligible participants:

- Searching of clinic records and operating lists by the clinical care team to identify individuals that may be eligible to enter the study
- Identification during trauma/fracture clinic visits by the clinical care team

12.1.1 Identification of participants via clinic records/hospital database

Potentially eligible patients will be identified by searching of clinic records/hospital databases at participating research sites by those in the clinical care team only. Any patients who are thought to fulfil the inclusion/exclusion criteria will be approached by their clinical care team in the trauma/fracture clinic on behalf of the research team.

12.1.2 Identification of participants during routine clinic visits

Potentially eligible patients identified during clinic visits will be provided with a Participant Information Sheet (PIS) by a member of their clinical care team (who may also be a member of the site research team) and asked to consider the study. Where their standard care clinician is not a member of the site research team potential participants will be asked if it would be acceptable for their name and contact details to be passed to the site research team who will make contact (this may be in person in a clinic or via telephone or video call in accordance with local site practice). Alternatively, potential participants may be given the PIS and asked to call the number on it if they wish to find out more about the study. When a potential participant is approached for permission for their details to be passed onto the site research team – if this permission is given this must be recorded in their clinical notes.

13 STUDY INTERVENTIONS

If there are multiple fractures in the same hand/wrist that require K-wire fixation, then all fractures should be treated in accordance with the randomised allocation (i.e. all wires buried or all wires exposed).

13.1 Fracture fixation with buried K-wires

Participants randomised to fixation with buried K-wires will undergo operative management (main theatre) of any phalangeal, metacarpal, carpal distal radius or ulna fracture, with K-wire(s) fixation. The K-wire ends are then cut and buried beneath the skin. The skin is then closed primarily. A dressing/cast will be applied. Exact surgical technique (including peri-operative management), use of peri-operative antibiotics, use of dressings (inc. antimicrobial), use of sutures (inc. antimicrobial),

and use of any immobilisation will be left to the discretion of the treating clinical team. Rehabilitation will be as per usual practice at each site. Details will be recorded.

13.2 Fracture fixation with exposed K-wires

Participants randomised to fixed with exposed K-wires will undergo operative management (main theatre) of any phalangeal, metacarpal, carpal, distal radius or ulna fracture, followed by fixation with K-wires that are left exposed above the skin. The ends are bent and protected as per usual practice of the treating clinical team. A dressing/cast will be applied. Exact surgical technique (including peri-operative management), use of peri-operative antibiotics, use of sutures and dressings (inc. antimicrobial), and use of any immobilisation will be left to the discretion of the treating clinical team. Rehabilitation will be as per usual practice at each site. Details will be recorded.

13.3 Post-operative care

Participants will be informed of their treatment group post operatively. Post-operative care will be as per the hospitals usual practice. Details of clinical visits and follow-up care will be recorded. Use of post-operative antibiotics will be at the discretion of the treating clinical team.

14 INFORMED CONSENT

14.1 Consent Procedure

Eligible patients will be identified and approached by a member of the patient's usual clinical care team (which may include the PI). The PI or appropriate delegate, e.g. from the research team or a member of the patient's usual care team, will then inform the patient of all aspects pertaining to participation in the study. If the patient is interested, they will be provided with the PIS and a verbal explanation of the trial procedures. It will be explained that entry into the trial is voluntary and that their treatment and care will not be affected by their decision. It will also be explained that they can withdraw at any time. In the event of their withdrawal, data collected prior to withdrawal will be retained and used in the analysis. The patients will be given the opportunity to discuss any issues related to the trial with the site research and clinical teams, as well as members of their family and friends. If willing to participate, patients will be asked to sign a consent form.

14.2 Time allowed to decide to take part

It is anticipated that participants will consent during the same clinic visit that they are approached to take part in the study due to the need to plan their treatment urgently, however they will be allowed as much time as possible to decide whether to take part or not as long as they consent within the permitted timeframes as per the in and exclusion criteria. They will also be able to consent on the day of surgery. Participants that consented in fracture/hand clinic, will be asked to confirm their consent verbally on the day of surgery, before further eligibility checks for randomisation take place.

14.3 Completion of the Informed Consent Form (ICF)

The potential participant and the PI (or authorised designee) must personally sign and date the current approved version of the ICF before any study specific procedures are performed. The ICF will usually be offered to patients in clinic as an electronic form on a tablet device (with the consent form being filled in directly on REDCap). Where it is not possible for a consent form to be completed in clinic (for example, if a patient has only had telephone appointments), remote electronic consent may also be used.

Where ICFs are completed electronically signatures will be either achieved by a finger tracing across a tablet device, using an electronic stylus on a tablet device or using a mouse dragging the cursor across the screen – all methods are to be used as if signing with a traditional pen. Where electronic

consent is used and the participant has an email address they are willing to provide, an electronic version of the signed ICF will be automatically emailed to them. If the participant does not have/does not provide an email address the site research team will be able to print a copy of the signed ICF and provide this to the participant. A downloaded copy of the electronic consent must be placed in the ISF and a copy in the participant's medical record.

14.4 Optional aspects of consent

Eligible individuals who agree to participate in the study, will also be asked to consider giving consent to the following optional aspects of the study:

With the participant's consent, the following identifiers will be retained: DOB and NHS/CHI/H&C number, as well as other routinely collected medical data where this relates to their injury, their treatment and/or their recovery, will be kept for ten years to use in future funded ethically approved research by the University of Oxford in relation to this study for the purpose of linking to routinely collected healthcare data. Participation in these elements of the research is voluntary and refusal to participate will not affect their inclusion in the study. Declining participation will not affect the healthcare they receive or their legal rights.

14.5 Individuals lacking capacity to consent

Individuals lacking capacity to consent to study participation will not be eligible to enter the study

14.6 GP notification

Both procedures are current practice in the NHS and therefore GPs do not need to be explicitly informed of the participants' participation in the study.

14.7 Re-consenting

Should there be any subsequent amendment to the final protocol, that might affect a participant's participation in the study, continuing consent will be obtained using an amended consent form which will be signed by the participant.

14.8 Participants who lose capacity during the study

Participants who consent and are included in the study who lose capacity during the study will be withdrawn and have their data available for use up until the point when they lose capacity. After this point ongoing consent is not valid.

15 RANDOMISATION

15.1 Timing of randomisation

Randomisation will be performed in the operating theatre, once eligibility has been confirmed. Informed consent and baseline questionnaires will have been completed prior to surgery.

15.2 Randomisation procedure

Participants will be randomised by the site research team or central study team using REDCap.

Participants will be randomised to one of the groups described in section 13.

Upon randomisation of a participant, the central study team and a member of the site research team will be notified by an automated email.

Full details of the randomisation procedure will be stored in the Randomisation and Blinding Plan in the confidential statistical section of the eTMF.

15.3 Randomisation methodology

Participants will be randomly allocated to the treatment options via automated, secure (encrypted), 24-hour, web-based randomisation provided by the OCTRU using a REDCap platform. Stratification will be used with random permuted blocks within each stratum with an allocation ratio of 1:1.

Allocation will be stratified to ensure balance for site, open/closed injury and anatomical location (hand/wrist). If there are multiple fractures covering both the hand and wrist, allocation will be stratified based on the injury that is randomised into the study.

15.3.1 Justification for stratification factors

Stratification by research site will help to ensure that any effect related to the research site itself will be equally distributed in the trial groups. While it is possible that the surgeons at one research site may be more experienced in one or other treatment than those at another research site, all of the research sites and indeed all hospitals throughout the NHS, use both techniques as part of their normal practice and generally, staff and surgeons will already be familiar with both forms of treatment.

Open/closed injury at presentation and anatomical location have a theoretically different baseline risk of SSI according to historical literature.

15.4 Back-up randomisation/registration procedure

There is no back-up randomisation procedure for this study as concluded in the risk assessment.

16 STUDY ASSESSMENTS/PROCEDURES AND DATA COLLECTION

The study flow chart can be found in Appendix 1 of this protocol.

16.1 Study Assessments/Data collection

For a full list of data collection, please see Appendix 2.

16.2 Procedure and method of study questionnaire completion

Participants will be emailed a link to complete their study questionnaires electronically where possible (participants will be asked at their baseline visit whether they wish to complete follow-up questionnaires electronically or on paper with postal return). Any links sent to a participant either by email or text to a questionnaire is unique to a participant and their timepoint/questionnaire in the study. Paper or telephone administered questionnaires may also be used where use of electronic means is not possible or suitable. Where paper-based questionnaires are used, data will be entered into REDCap by the central study team. Participants may be sent up to two reminder messages. Participants that do not complete their study questionnaires may be telephoned by a member of the central study team to collect the data or request return of the questionnaire.

16.3 Withdrawal and change to consent

Withdrawal of consent means that a participant has expressed a wish to withdraw from the study altogether or from certain aspects of the study only. The type of withdrawal will be collected on the Case Report Form (CRF) labelled 'Withdrawal'.

The Withdrawal CRF must be completed to document the reasons for withdrawal and state who made the decision to withdraw. Discussions and decisions regarding withdrawal must be documented in the participant's medical notes. The PI (or delegate) must continue to follow up any Serious Adverse Events (SAEs) and continue to report any SAEs to resolution in the CRF in accordance with the safety reporting section of this protocol.

Where a participant expresses a wish to withdraw from the study, the research team will determine which aspect(s) of the study the participant wishes to withdraw from.

The aspects of the study that the participant may request to withdraw from are as follows:

- No longer willing to receive study intervention
- No longer willing to complete study questionnaires
- No longer willing to have routine data from the medical record provided to the study

In addition to participant self-withdrawal, the PI (or delegate) may decide to withdraw a participant from the study intervention for clinical reasons or other reasons such as eligibility. Participants will still be asked to participate in the collection of follow-up data. The reason for withdrawal will be recorded on the study Withdrawal CRF.

Completion of the Withdrawal CRF will be done by to the central study team. Appropriate action will be taken by the study teams (centrally at the CTU and by the site research team at each research site) to ensure compliance with the participant's withdrawal request. This may include marking future CRFs as not applicable and ensuring any relevant communications which the participant had consented to receive regarding their participation are no longer sent.

Data collected up to the point of withdrawal will be used/analysed as explained in the PIS.

17 TRANSLATIONAL/ MECHANISTIC RESEARCH

There are currently no planned sub-studies/translational studies/mechanistic studies.

18 QUALITATIVE RESEARCH

No qualitative research will be performed as part of the study.

19 BLINDING AND CODE BREAKING

19.1 Blinding

There is no blinding of the intervention in this study

19.2 Code break/unblinding

Not applicable for this study.

20 STUDY SAMPLES

This study protocol does not involve any taking of new biological samples or any use of pre-existing samples.

21 IMAGING

This study protocol does not involve any imaging.

22 SAFETY REPORTING

22.1 Safety reporting period

Safety reporting for each participant will begin from the first point of administration of the intervention and will end when the participant has reached their final main follow-up time point, at 6 months post-randomisation.

22.2 Definitions

Table 3: Definitions

An adverse event (AE)	Any untoward occurrence in a clinical study participant. *Note: An AE can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding, for example), symptom or disease temporarily associated with the study procedures, whether or not considered related to the procedures.*
Related AE	An event that resulted from administration of any of the research procedures
SAE	An SAE is any untoward medical occurrence that: • results in death • is life-threatening[1] • requires inpatient hospitalisation or prolongation of existing hospitalisation • results in persistent or significant disability/incapacity • is a congenital anomaly/birth defect • is otherwise considered a medically important event by the Investigator[2]
Unexpected Related SAE	An SAE related to the study (i.e. resulted from administration of any of the research procedures) and is unexpected (not listed in the protocol as an expected occurrence).

[1] participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

[2] Other 'important medical events' are any events that may jeopardise the participant or may require medical or surgical intervention to prevent one of the above outcomes listed above.

A distinction is drawn between serious and severe AEs. Severity is a measure of intensity whereas seriousness is defined using the criteria above. Hence, a severe AE need not necessarily be serious.

22.3 Expected AEs

This is a low risk, pragmatic trial where both study interventions are in common use. For this trial, foreseeable AEs will not need to be reported immediately, but will be recorded on participant and site reported CRFs or an AE form. They include the following:

- Complications of anaesthesia
- Complications of surgery
    - Wire loosening leading to unplanned removal of the wires (both groups)
    - Wire erosion through skin leading to unplanned removal of the wires (buried group only)
    - Wire loss/falling out before removal by clinical team
    - Wire breaking while in situ resulting in unplanned removal or need for re-fixation
    - Damage to nerves, tendons or blood vessels
    - Scar related complications (hypertrophic, keloid, pigmented)
    - Bone related complications (mal-union, non-union)
    - Clinical diagnosis of complex pain syndrome documented in the participant's medical record.
- Further surgery for SSI
    - Loss of fracture position/malunion
    - Removal of symptomatic metalwork
    - Other surgery related to the fracture or its management

22.4 Recording and reporting of AEs/SAEs

Only those AEs that meet the definition of SAEs, are not listed as foreseeable AEs, and are considered by the site investigator to be related (possibly, probably, or definitely, see Table 4) to the trial intervention or any of the research procedures will be reported immediately to the central trial team as follows:

SAEs will be reported by the site research team using the SAE form within the REDCap trial database as soon as they are aware of the event. The central trial team is automatically notified of the SAE report through the database. A paper SAE form will be used as a back-up if the SAE form is not available electronically. This must be emailed to hawaii-drift@ndorms.ox.ac.uk within 24 hours of becoming aware of the event. The central study team will acknowledge receipt of any SAEs reported via email within one working day and provide the site with a unique SAE Log number.

22.5 Events exempt from immediate reporting as a SAE

AEs that are unrelated to the intervention will not be reported. AEs deemed related to the intervention that do not meet the SAE definition as per section 22.3. will also not be reported.

22.6 Procedure for collecting safety events from sites/participants

Complications will be recorded on participant-reported questionnaires and/or by the site investigators in the 'Complications' CRF if they become aware of such an event.

22.7 Follow-up of SAEs

A follow-up report must be completed when the SAE resolves, is unlikely to change, or when additional information becomes available. If the SAE is an unexpected, related event then additional follow-up information must be provided as requested by the central study team.

22.8 Assessment of SAEs by the PI (or delegate)

The PI (or delegated individual) is responsible for assessing all reported SAEs for seriousness, causality and expectedness.

22.8.1 Relatedness/causality

The assessment of "relatedness" to the study intervention is the responsibility of the PI at site or an agreed designee according to the following definitions:

Table 4: Relatedness/causality

Relationship to intervention	Attribution (Causality)	Description
Unrelated	Unrelated	The AE is clearly NOT related to the intervention
	Unlikely	The AE is doubtfully related to the intervention
Related	Possible	The AE may be related to the intervention
	Probable	The AE is likely related to the intervention
	Definite	The AE is clearly related to the intervention

22.9 Review of SAEs by the Sponsor/Clinical Trial Unit (CTU) Nominated Person

An appropriately qualified person will review the SAE and raise any queries with the reporting site. If the site has not provided an assessment of causality and has not responded to the query, it will be assumed that the event reported is related to the study procedures/intervention. The reporting site will be encouraged to respond and if a response is not provided the CI will be consulted by the CTU and the CTU will complete the Sponsor part of the SAE report.

22.10 Reporting of SAEs to the Research Ethics Committee (REC)

All SAEs that are assessed as related and unexpected will be submitted to the REC within 15 days of the CTU/Sponsor becoming aware of the event.

22.11 Unblinding of SAEs for reporting to the REC

Not applicable. There is no blinding in this study.

23 PREGNANCY

If a participant does become pregnant during their participation in the study, it does not need to be reported due to the nature of the intervention.

24 STATISTICAL CONSIDERATIONS

All statistical analyses will be carried by the statisticians based at OCTRU. A single trial analysis is planned once the study has completed recruitment and follow-up of participants. Study analysis will follow the outline presented in the statistical analysis plan (SAP).

24.1 SAP

The statistical aspects of the study are summarised here with details fully described in a SAP that will be drafted early in the study and finalised prior to the final analysis data lock, or any planned interim comparative analyses. The SAP will be written by the Study Statistician in accordance with the current OCTRU SOPs. The Trial Oversight Committee (TOC) will review and, if necessary, provide input into the SAP.

24.2 Sample Size/Power calculations

440 participants, 220 in each group, will be required for 80% statistical power at the two-sided 5% significance level to detect an absolute reduction of 8% (14% vs 6%). Through previously performed studies on SSI rates (WHISH, WHiTE 8 COPAL).(19, 20) we have established that rates of available data are high and as such only a relatively small number of additional participants need to be

recruited to ensure sufficient data is collected. Allowing for 6% missing data, recruiting 470 participants is planned.

24.3 Description of Statistical Methods

Standard statistical summaries will be presented for all outcome measures. Baseline data will be summarised and visually compared to check comparability between treatment arms. Methods of analysis for the primary and secondary outcomes are briefly described below. All analyses will be conducted at the 2-sided 95% significance level unless otherwise stated. It is anticipated that all statistical analysis and data cleaning will be undertaken using R (www.r-project.org) and/or Stata (StataCorp LP, www.stata.com). Results will be reported in line with the Consolidated Standards of Reporting Trials (CONSORT) statement and any appropriate extensions and will be described fully in a separate SAP.

24.3.1 Primary outcome

A participant will be considered to have had an SSI if they were treated using systemic antibiotics (oral, intravenous or topical). The odds of surgery site infection will be analysed using logistic regression adjusting for the allocated treatment, randomisation factors, and known variables that affect SSI risk (open vs closed fracture, wrist vs hand, diabetes mellitus/immunosuppression therapy). Estimates of the odds ratio with corresponding 95% confidence intervals and p-values will be presented. An unadjusted analysis will also be conducted using logistic regression, and in the presence of convergence issues (indication of reliable results due to low number of events), the adjustments made in the main primary outcome analysis will also be simplified as necessary.

24.3.2 Secondary outcome(s)

Linear regression will be used to analyse the PROMIS UE and EQ-5D-5L (utility and EQ-VAS) secondary outcomes at 90 days and 6 months after randomisation. All models will adjust for baseline levels as well as the treatment and randomisation levels. Complications will be compared using the same model as the primary outcome.

Estimates of the treatment effect, 95% confidence intervals and p-values will all be reported.

24.4 Inclusion in analysis

The principal analysis of all outcomes will be performed on the as-randomised (“intention to treat”) population, analysing participants with available outcome data in their randomised groups, regardless of adherence reflecting a focus on a treatment policy estimand. The study will be reported in line with CONSORT guidelines.

A per protocol analysis set will be used for a secondary analysis of the primary outcome which only includes those who received the randomised intervention as allocated. While in-theatre randomisation is being used to limit the proportion of non-compliance, they are still expected to occur in a small percentage of participants who do not receive the allocated intervention.

24.5 Subgroup analysis

We will perform subgroup analyses for hand versus wrist fractures, open versus closed fractures, and infections with or without prophylactic antibiotics. These will be analysed at the 2-sided 95% significance level but will be reported as pre-planned “exploratory” analyses. Further details are given in the latest version of the SAP.

24.6 Interim analyses

The main outcomes will be analysed as stated in the analysis plan once the study follow-up has been completed. No formal interim analyses of treatment effect are planned for any of the study outcomes.

24.6.1 Stopping rules

No formal interim analyses are planned and no stopping rules have been incorporated into the study design. An independent TOC will review the accumulating data at regular intervals and may recommend pausing or stopping the study in the event of safety concerns.

24.7 Level of Statistical Significance

All treatment comparisons will be reported with 95% confidence intervals and a 2-sided significance level of 5% will be used to test statistical significance.

24.8 Procedure for accounting for missing data

The procedure for handling missing data will be described in the SAP. The study will attempt to collect data as completely as possible. The sample size calculation incorporated an inflation of 6% to account for potential loss to follow-up or participant death. The main analyses will all be on complete case analysis. A sensitivity analysis will explore the impact of missing data on the primary outcome and full details will be confirmed in the SAP.

Critical data is outlined in the DMP and will be of primary importance for collection teams.

24.9 Procedures for reporting any deviation(s) from the original SAP

Any deviation from the original SAP will be described in the final statistical report. Additional analyses that are not pre-planned will be reported as “post-hoc”.

24.10 Internal pilot/Decision Points

There will be no internal pilot or decision points.

25 HEALTH ECONOMICS

A prospective within-trial economic evaluation comparing the cost-effectiveness of buried vs. exposed K-wires among participants with hand and wrist fractures will be conducted from the National Institute for Health and Care Excellence (NICE) recommended NHS and personal social services perspective at six-months post-randomisation.(44) A health economic analysis plan will be drafted, reviewed by the TOC and finalised before unblinding. The within-trial economic evaluation will be reported according to the Consolidated Health Economic Evaluation Reporting Standards 2022. (21)

Data will be collected on the health and social service resources used in the treatment of each trial participant during the period between randomisation and 6 months post-randomisation. A site-reported CRF will record the intervention (antibiotics and/or procedure) due to SSI up to 6 months post-randomisation. Additionally, participant-reported questionnaires will record treatment (antibiotics, further hospital treatment including surgery) received for a wound infection at the site of their fracture fixation. At 90 days and 6 months post-randomisation, trial participants will be asked to complete questionnaire profiling hospital (inpatient, outpatient and accident and emergency) and community health and social care resource use and, for the purposes of sensitivity analysis, out-of-pocket expenditures and costs associated with lost productivity. Unit costs will be applied from the latest available reference sources. Utilities will be estimated from EQ-5D-5L descriptive system using the latest value set recommended by NICE and be used to generate quality adjusted life-years (QALYs).(22) Mechanisms of missingness of data will be explored and multiple

imputation will be adopted if data is missing at random. Cost and QALY estimates will be bootstrapped and adjusted for randomisation variables (research site, anatomical location of injury, and open vs. closed injuries) and other potential variables as per the SAP. Results will be presented using Incremental Cost-Effectiveness Ratios and compared against the NICE recommended cost-effectiveness threshold of £20,000 to £30,000 per QALY. (22) An additional £15,000 cost-effectiveness threshold will also be included to reflect recent trends in health-care decision-making.(23)

Uncertainty in costs and QALYs will be assessed using bootstrap credible intervals, with the probability of cost effectiveness at different cost-effectiveness thresholds values represented using cost-effectiveness acceptability curves. Deterministic sensitivity analysis will also be performed. First, a societal perspective that includes lost productivity will be considered. Second, a complete-case analysis in which only participants with completed data on all cost and outcome data at all follow-up time points will be performed.

26 DATA MANAGEMENT

The data management aspects of the study are summarised here with details fully described in the study-specific DMP. See section 30 for information on management of personal identifiable data.

CRFs will be designed by the Trail Management Team (TMT). All electronic patient-identifiable information will be held on a secure, password-protected database accessible only to essential personnel. Participants will be identified by a code number only. Direct access to source data/documents will be required for study-related monitoring.

26.1 Source Data

Source documents are where data are first recorded, and from which participants' CRF data are obtained. CRF entries will be considered source data if the CRF is the site of the original recording (e.g. there is no prior written or electronic record of data). Source data for the study is detailed in the tables within section 9 and defined further within the study DMP.

26.2 CRFs

PIs and study site staff will ensure that data collected on each participant is recorded in the CRF as accurately and completely as possible. Details of all protocol evaluations and investigations must be recorded in the participant's medical record for extraction onto the CRF. All summary reports will be transcribed into the CRFs from the relevant source data held in the site medical record(s).
All documents will be stored safely in confidential conditions. On all study-specific documents, other than the signed consent, the participant will be referred to by the study participant number/code, not by name.

26.3 Non-CRF data

All study data will be recorded on the CRF. No additional data will be held outside of the CRFs.

26.4 Access to Data

Members of the study team will only be able to access data that they need to, based on their roles and responsibilities within the study.

Direct access to source data/documents will be required for study-related monitoring and/or audit by the Sponsor, research team or NHS Trust or regulatory authorities as required.

The data submitted by study participants directly in REDCap (i.e. electronic participant reported outcomes) will also be made available to the research site that recruited the participant; this is detailed within the PIS so that participants are aware of who will have access to this data.

26.5 Data Recording and Record Keeping

The CRFs will be designed by members of the study management team which will include the CI, study statistician(s), health economist and study manager.

Data will, wherever possible, be collected in electronic format with direct entry into REDCap by site staff or participants. Electronic data collection has the major advantage of building "data logic" into forms, minimising missing data, data input errors and ensuring the completeness of consent and assent forms. REDCap is a secure, web-based application designed to support data capture for research studies, providing 1) an intuitive interface for validated data entry; 2) audit trails for tracking data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for importing data from external sources.

All data entered will be encrypted in transit between the client and server. All electronic patient-identifiable information, including electronic consent forms, will be held on a server located in an access-controlled server room at the University of Oxford.

The data collection system and server are backed up to a secure location on a regular basis. Details of the data collected, where it is stored and who has access to it along with a fair processing statement will be available for the participants within the study PIS.

Data captured during phone calls to participants or from paper-based study questionnaires returned to the central study team will be entered into REDCap by suitably trained central study team staff. Full details of this process will be recorded in the DMP. Identifiable data will only be accessible by members of the research team with a demonstrated need (managed via access controls within the application) and only used to communicate with the participant (i.e., for sending follow-up reminders and/or for online form completion or telephone follow-up).

26.6 Electronic transfer of data

Any electronic transfer of data within the University of Oxford or from the University of Oxford to external parties during the course of the study will be strictly controlled in accordance with the OCTRU SOP for Secure Information/Data Transfer.

27 QUALITY ASSURANCE (QA) PROCEDURES

A rigorous programme of quality control will be implemented. The Trial Management Group (TMG) will be responsible for ensuring adherence to the study protocols at the research sites. QA checks will be undertaken by OCTRU to ensure integrity of randomisation, study entry procedures and data collection. OCTRU has a QA team who will monitor this study and conduct audits in accordance with their SOPs. Furthermore, the processes of obtaining consent, randomisation, registration, provision of information and provision of treatment will be monitored by the central study team. Additionally, the study may be monitored or audited by Sponsor or host sites in accordance with the current approved protocol, GCP, relevant regulations and SOPs.

A study-specific data management and monitoring plan will be in place prior to the start of the study.

27.1 Risk Assessment

This protocol is designed to deliver a risk-adapted approach to conducting the research. A risk assessment has been conducted and a monitoring plan will be prepared before the study opens. The known and potential risks and benefits to participants have been assessed in comparison to those of standard of care. A risk management strategy is in place and will be reviewed and updated as

necessary throughout the study or in response to outcomes from monitoring activities. Monitoring plans will be amended as appropriate.

27.2 Study monitoring

Monitoring will be performed by the central study team according to a study-specific monitoring plan. Data will be evaluated for compliance with the protocol, completeness and accuracy. The investigator and institutions involved in the study will permit study-related monitoring and provide direct on-site access to all study records and facilities if required. They will provide adequate time and space for the completion of monitoring activities.

Research sites will be monitored centrally by checking incoming data for compliance with the protocol, consistency, completeness and timing. The CRF data will be validated using appropriate set criteria, range and verification checks. The study site must resolve all data queries in a timely manner. All queries relating to key outcome and safety data and any requiring further clarification will be referred back to the study site for resolution.

Research sites will also be monitored remotely and/or by site visit, as necessary, to ensure their proper conduct of the study. Central study team staff will be in regular contact with site personnel to check on progress and deal with any queries that they may have. Any monitoring reports/data discrepancies will be sent to the site in accordance with OCTRU SOPs and the study monitoring plan. The Investigator is expected to action any points highlighted through monitoring and must ensure that corrective and preventative measures are put into place as necessary to achieve satisfactory compliance, within 28 days as a maximum, or sooner if the monitoring report requests.

27.3 Audit and regulatory inspection

All aspects of the study conduct may be subject to internal or external QA audit to ensure compliance with the protocol, GCP requirements and other applicable regulation or standards. Such audits may occur at any time during or after the completion of the study. Investigators and their host Institution(s) should understand that it is necessary to allow auditors direct access to all relevant documents, study facilities and to allocate their time and the time of their staff to facilitate the audit visit. Anyone receiving notification of an audit that will (or is likely to) involve this study must inform the central study team without delay.

27.4 Trial committees

27.4.1 TMG

A TMG will be established for the study and operate in accordance with a study-specific TMG charter. The TMG will manage the trial, including the clinical and practical aspects and will meet approximately monthly to assess progress. Other specialities/individuals will be invited as required for specific items/issues.

27.4.2 Trial Oversight Committee (TOC)

The Trial Oversight Committee (TOC), which includes independent members, provides overall supervision of the trial on behalf of the funder. Its terms of reference will be drawn up in a TOC DAMOCLES based charter which will outline its roles and responsibilities. Meetings of the TOC will take place at least once a year during the recruitment period. An outline of the remit of the TOC is to:

- Monitor and supervise the progress of the study towards its interim and overall objectives

- Review accruing data, completeness and blinded summaries if required and will assess the screening algorithm against the eligibility criteria
- Consider emerging evidence from other related studies or research
- Review any safety issues and make recommendations as to whether the protocol should be amended to protect participant safety
- Inform the funding body on the progress of the study

The TOC will include at least one Patient and Public Involvement (PPI) representative as an independent member. Full details including names will be included in the TOC Charter.

28 IDENTIFICATION AND MANAGEMENT OF RESEARCH SITES

28.1 Identification of recruitment sites

Recruitment sites will be selected based on suitability to conduct the study. Potential sites will be invited to complete a site feasibility questionnaire which will be used by the TMG to assess suitability of the site for the study; the suitability assessment will primarily be based on the resources available at site and the feasibility of meeting recruitment targets.

28.2 Study site responsibilities

The PI has overall responsibility for the conduct of the study but may delegate responsibility where appropriate to suitably experienced and trained members of the site research team. All members of the site research team must complete delegation log provided by the central study team prior to undertaking any study duties. The PI must counter sign and date each entry in a timely manner, authorising staff to take on the delegated responsibilities.

28.3 Study site set up and activation

The PI leading the research site is responsible for providing all required core documentation. Mandatory site training which is organised by the central study team (see below) must be completed before the site can be activated. Training in the study processes will be administered at site initiation visits delivered either in person or online by the central study team. The central study team will check to confirm that the site has all the required study information/documentation and is ready to recruit. The site will then be notified once they are activated on the REDCap data collection system and are able to begin recruiting participants.

28.4 Training

Training in the study processes will be administered at site initiation visits by the central study team.

28.5 Study documentation

The central study team will provide an electronic ISF to each research site containing the documents needed to conduct the study. The central study team must review and approve any local changes made to any study documentation including PIS and consent forms prior to use. Additional documentation generated during the course of the study, including relevant communications must be retained in the site files as necessary to reconstruct the conduct of the study.

29 ETHICAL AND REGULATORY CONSIDERATIONS

The study will be conducted in compliance with the approved protocol, the Declaration of Helsinki, the principles of GCP, the UK Data Protection Regulation (UK GDPR) and all other applicable regulatory and governance frameworks including the UK policy framework for health and social care research.

29.1 Summary of study-specific considerations

There are no study-specific considerations.

29.2 Ethical conduct of the study and ethical approvals

The full trial protocol, ICF, PIS and advertising material and patient-facing intervention materials will be submitted for approval to a National NHS REC, Health Research Authority (HRA), and host institutions. Based on the extensive experience of the applicant team in conducting similar trials in trauma and rehabilitation, no major ethical concerns are anticipated. The randomised clinical trial will not commence until thorough checks of all documentation and approvals have been completed by OCTRU. No Clinical Trials Authorisation is needed for this study.

The protocol, PIS, ICF and any other information that will be presented to potential study participants (e.g. advertisements or information that supports or supplements the informed consent process) will be reviewed and approved by an appropriately constituted, independent REC.

29.3 NHS Research Governance

Once HRA & Health and Care Research Wales approval is in place for the study, sites will confirm capability and capacity to participate in the study.

29.4 Protocol amendments

All amendments will be generated and managed according to OCTRU SOPs to ensure compliance with applicable regulation and other requirements. Written confirmation of all applicable REC and local approvals must be in place prior to implementation by Investigators as applicable for the amendment type. The only exceptions are for changes necessary to eliminate an immediate hazard to study participants (see below).

It is the PIs responsibility to update participants whenever new information becomes available that might affect the participant's willingness to continue in the study. The Investigator must ensure this is documented in the participant's medical notes and the participant is re-consented if appropriate

29.5 Protocol Compliance and Deviations

Protocol compliance is fundamental to GCP. Prospective, planned deviations or waivers to the protocol are not allowed. Changes to the approved protocol need prior approval unless for urgent safety reasons.

A study related deviation is a departure from the ethically approved study protocol or other study document or process or from GCP or any applicable regulatory requirements. Deviations from the protocol will be captured in REDCap using either using a protocol deviation form or via suitably designed fields within the CRF which will be extracted from REDCap and reviewed regularly by the TMG. Deviations will be handled and reviewed in a timely manner in accordance with the study central monitoring plan.

The PI or a member of the research team must promptly report any deviation from GCP or protocol to the central study team. This includes important deviations which are those that might impact participant safety, primary/ secondary endpoint data integrity, or be a possible serious breach of GCP (see section 29.8).

Any third parties conducting study-specific procedures must also report any deviations directly to the central study team.

29.6 Urgent safety measures

The Sponsor or PI (or delegate) may take appropriate urgent safety measures to protect study participants from any immediate hazard to their health or safety. Urgent safety measures may be taken without prior authorisation. The study may continue with the urgent safety measures in place. **The Investigator must inform the central study team IMMEDIATELY if the study site initiates an urgent safety measure:**

The notification must include:

- Date of the urgent safety measure;
- Who took the decision; and
- What action was taken and why

The PI (or delegate) will provide any other information that may be required to enable the central study team to report and manage the urgent safety measure in accordance with the current regulatory and ethical requirements for expedited reporting and close out. The central study team will follow written procedures to implement the changes accordingly.

29.7 Temporary halt

The Sponsor and Investigators reserve the right to place recruitment to this protocol on hold for short periods **or** to declare a temporary halt. A temporary halt is defined as a formal decision to:

- interrupt the treatment of participants already in the study for safety reasons;
- stop recruitment on safety grounds; or
- stop recruitment for any other reason(s) considered to meet the substantial amendment criteria, including possible impact on the feasibility of completing the study in a timely manner.

The central study team will report the temporary halt to the REC via an expedited substantial amendment procedure. The study may not restart after a temporary halt until a further substantial amendment to re-open is in place. If it is decided not to restart the study this will be reported as an early termination.

29.8 Serious Breaches

A “serious breach” is a breach of the protocol or of the conditions or principles of GCP which is likely to affect to a significant degree –

(a) the safety or physical or mental integrity of the study subjects; or

(b) the scientific value of the research.

Investigators must notify the central study team within one working day if any serious breach of GCP is suspected. The central study team will review the event and, if appropriate will report a serious breach to the REC and the NHS host organisation within 7 days of the central study team becoming aware of the breach.

29.9 Study Reports

This protocol will comply with all current applicable REC and Sponsor reporting requirements.

29.10 Transparency in Research

Prior to the recruitment of the first participant, the study will be registered on a publicly accessible database (https://www.isrctn.com/ISRCTN13920928), which will be kept up to date during the study, and results will be uploaded to the registry within 12 months of the end of the study declaration. A Final Report will be submitted to the REC containing a lay summary of the study results which will be published on the HRA website.

The results of the study will be published and disseminated in accordance with section 35.

29.11 Use of social media

Social media (e.g., Twitter feeds) may be utilised by the central study team to make general announcements about the study, and acknowledge when milestones are met (e.g., sites open to recruitment, first recruitment at a site etc).

30 PARTICIPANT CONFIDENTIALITY

30.1 Collection and use of personal identifiable data (PID)

Contact details (*e.g. e-mail addresses/postal addresses/phone number)* for participants will be collected in this study for the following purposes, and where an activity is optional, only with the specific consent of the participant:

- Sending of follow-up questionnaires and any reminder messages
- Sending text messages regarding follow-up questionnaires
- Sending a copy of the completed consent form by email (for any participants that wish to receive a copy by email)
- Sending of Welcome pack/reminder letters direct to participant's homes
- Collection of NHS/CHI/H&C number to check hospital records

The PIS explains what contact details will be collected and how these will be used. Where remote eConsent is used, participants will be asked to give their permission verbally for a link to the consent documentation to be sent to their email address or an email address they provide.
PID will be collected and used in this study as detailed in Table 5.

Table 5: Collection and use of personal identifiable data

Personal identifiable information collected	Planned use in study
Participant name	To send questionnaires/letters/contact by phone
Participant E-mail address	To send copy of consent form (for any participants that consent electronically and wish to receive a copy by email) To send follow-up questionnaires To send trial communications (such as welcome letters, reminder letters etc)
Participant phone number(s)	To send text messages regarding study questionnaires To contact participants regarding uncompleted study questionnaires and/or any queries
Participant's address	To send trial communications (such welcome letters and reminder letters etc) To send paper questionnaires (if postal option chosen)
Participant Date of Birth	Age calculation (eligibility criteria), to check hospital records (long term linkage)
Participant NHS/CHI/H&C number	To check hospital records (long term linkage)

The PIS explains what PID will be collected and how these will be used.

30.2 Use of audio /visual recording devices

Not applicable

30.3 Storage and use of personal data

During the study personal data will be stored and used in accordance with the OCTRU SOP for confidentiality, protection and breach of personal data in relation to research subjects. This ensures

that all personal data collected during the study is recorded, handled and stored in accordance with the requirements of the UK General Data Protection Regulation.

All electronic participant-identifiable information will be held on a secure, password-protected database accessible only to authorised personnel. The processing of the personal data of participants will be minimised wherever possible by the use of a unique participant study number on study documents and any electronic systems.

Personal data on all documents will be regarded as confidential. The study staff will safeguard the privacy of participant's personal data.

The use of all personal data in the study will be documented in a study-specific DMP which details what and where personal data will be held, who will have access to the data, when personal data will be anonymised and how and when it will be deleted.

The Investigator site will maintain the participant's anonymity in all communications and reports related to the research.

Data Breaches will be highlighted to the relevant site staff and reported as required by the UK GDPR and Data Protection Act 2018. This will also be deemed a protocol deviation.

30.4 Access to participants' personal identifiable data during the study

Access to participants personal identifiable data will be restricted to individuals authorised to have access. This includes a) members of the research team at participating research sites with delegated responsibility by the site PI and b) members of the central study team involved in the conduct/management of the study where this is necessary for their role.

Research staff that are not part of the potential participant's direct healthcare team will not have access to personal identifiable data until the individual has given their consent to take part in the study or the participant has indicated to their direct healthcare team that they wish to be contacted by a member of the site research team – permission for this will be recorded in the individual's medical notes.

The PIS clearly describes who will have access to the participants personal identifiable data during the study.

Participants will be asked to consent to relevant sections of their medical notes and data collected during the study being looked at by individuals from the University of Oxford, from regulatory authorities [and from the NHS Trust(s)], where it is relevant to their taking part in this study; only authorised individuals will be granted access where this is necessary for their role.

30.5 Destruction of personal identifiable data

Personal identifiable data will be destroyed as soon as it is no longer required – the time point for this destruction is detailed in the study DMP and is in accordance with OCTRU SOPs which comply with the UK GDPR. For those participants who have consented for their data to be retained for longer term linkage, relevant data will be stored securely at the University of Oxford .

30.6 Participant Identification Log

The site research team must keep a separate log of enrolled participants' personal identification details as necessary to enable them to be tracked. These documents must be retained securely, in strict confidence. They form part of the eISF and are not to be released externally.

31 PUBLIC AND PATIENT INVOLVEMENT

31.1 PPI in study design and protocol development

The surgical members of the team have a significant combined experience of working with and treating members of the public who have sustained hand and wrist fractures. The UK Trauma and Emergency Care PPI group has been involved in ongoing research prioritisation exercises over several years; the management of wrist fractures being a consistent priority.

A national survey of 187 patients who have had K-wires for hand fractures, showed that the way the wire ends are managed is an important issue for people. Further PPI work was undertaken as part of JW's NIHR DRF (as part of the original HAWAII feasibility study) to specifically refine research into wound infection following hand and wrist trauma surgery. Already debilitated by the initial injury, research into interventions to reduce subsequent infection leading to worse outcomes, was felt to be of considerable importance during our HAWAII focus groups. However, alongside assessing post-operative infection risk, our PPI group also felt that measurement of hand function and quality of life was also very important.

Bespoke input was sought from patients and the public via a named PPI team member. The PPI group will also be available to provide peer-support and wider review of materials. Patients and members of the public have already:

- Prioritised this research question through the James Lind Alliance.
- Confirmed the appropriateness of the outcome measures.
- Drafted and reviewed the plain English summary.
- Reviewed the grant application.

31.2 PPI in development of participant information

PPI will be involved throughout the study by:
(a) informing the development of patient facing documents,
(b) overseeing professional designers to produce appealing materials
(c) advising on the content of an explainer animations and web content

31.3 PPI during the study

A PPI representative will attend monthly TMG meetings. Another PPI member will be invited to attend the TOC.

32 EXPENSES/PAYMENTS TO PARTICIPANTS

All research activity is conducted during routine standard of care visits; no payments will be made to study participants for taking part in this study.

33 SPONSORSHIP, FINANCE, AND INSURANCE

33.1 Sponsorship

The Sponsor will provide written confirmation of Sponsorship.

33.2 Funding and support in kind

The funder of the study is NIHR-RfPB (NIHR207194).

33.3 Insurance

The Sponsor (University of Oxford) has a specialist insurance policy in place which would operate in the event of any participant suffering harm as a result of their involvement in the research *(Newline*

Underwriting Management Ltd, at Lloyd's of London). NHS indemnity operates in respect of the clinical treatment that is provided.

34 CONTRACTUAL ARRANGEMENTS

This study is subject to the Sponsor's policy requiring that written contracts/agreements are agreed formally by the participating bodies as appropriate.

Appropriate contractual arrangements will be put in place with all third parties.

35 PUBLICATION AND DISSEMINATION

The Sponsor will retain ownership of all data arising from the study.

Publication and dissemination of study results will be in accordance with OCTRU SOPs and irrespective of study findings.

The study protocol will be published in an open-access peer-reviewed journal in accordance with the Standard Protocol Items: Recommendations for Interventional Trials statement (SPIRIT, www.consort-spirit.org/). The study results will be published in an open-access journal, in accordance with the NIHR's policy on open-access research. The study will be reported following the guideline CONSORT including any applicable extensions to this. The Template for Intervention Description and Replication (TIDieR) statement will be used for reporting the intervention.

The SAP will be published in an open-access peer-reviewed journal before recruitment is completed.

The health economics analysis plan will be published in an open-access peer-reviewed journal before recruitment is completed.

35.1 Study results

All data will be presented such that no individual participants can be identified.

35.2 Informing participants of study results

A summary of the study results for study participants will be written collaboratively with clinicians and PPI and distributed accordingly. The PIS includes a link to the study website where participants will be advised that the results will be published via lay summaries and infographics. The study website and social media will share news on study progress. The PPI co-applicant, along with the wider PPI group, will support development of these lay summaries and use their contacts to reach wider patient networks. The GRIPP2 (Guidance for Reporting Involvement of Patients and the Public 2) will be used to aid high-quality reporting of PPI activities throughout the project dissemination.

35.3 Dissemination of study results

Dissemination of results will include the following methods:

Conference: The results of this study will be disseminated to the clinical community via presentations at national and international meetings. Traditional conference dissemination will focus on presentations to include the key professional stakeholders. It is expected that findings from this study will be presented at multiple conferences.

Publications: Results will usually be published in peer-reviewed journals. Where possible, plain English summaries will be published alongside the full paper, along with links to other digital media on the study website to explain the study result in an accessible format – i.e. an explainer video and infographic.

Public Dissemination: To ensure a broad campaign range of social media outlets will be targeted (this may include an explainer video and infographic). Engagement with the NHS Dissemination centre will be sought and a 'digital story' will be published as part of the 'NIHR Signal'.

The wider public will be alerted via links with relevant organisations/charities, and the Research Media Offices. Engagement with the NIHR Dissemination Centre will also be sought, to ensure global awareness of study findings. Moreover, the University of Oxford and Oxford University Hospitals NHS Trust have professional communication officers. It is anticipated that together these individuals, and NIHR equivalents will agree upon effective communication strategies including co-ordinated press releases, interviews etc.

35.4 Authorship

Authorship of any publications arising from the study will be determined in accordance with the ICMJE guidelines and any contributors acknowledged accordingly.

All publications arising from this study must acknowledge the contribution of participants, funder(s), OCTRU, HAWAII-DRIFT study group and the Sponsor.

36 DEVELOPMENT OF A NEW PRODUCT/PROCESS OR THE GENERATION OF INTELLECTIAL PROPERTY (IP)

Ownership of IP generated by employees of the University vests in the University. The University will ensure appropriate arrangements are in place as regards any new IP arising from the study.

37 ARCHIVING

37.1 Archiving period

The archiving period for essential study documents for this study is three years following publication of the main study results. Participating research sites must not archive or destroy study essential documents without written instruction from the central study team.

37.1.1 Retention of documents/information beyond the mandatory archiving period

With the participant's consent, the following identifiers will be retained: DOB and NHS/CHI/H&C number, as well as other routinely collected medical data where this relates to their injury, their treatment and/or their recovery, this will be kept for ten years after the end of the study to use in future funded ethically approved research by the University of Oxford in relation to this study for the purpose of linking to routinely collected healthcare data. The data will be stored electronically in a suitable format in a secure server area maintained and backed up to the required standard and accessible only to authorised members of the research team. Should participants want to withdraw from this at a later stage they can do so by contacting the central study team. All other identifiers will be removed in line with section 30.5.

37.2 Archiving responsibilities/procedure

During the study and after study closure the PI must maintain adequate and accurate records to enable the conduct of the clinical study and the quality of the research data to be evaluated and verified. All essential documents must be stored in such a way that ensures that they are readily available, upon request for the minimum period as specified above.

37.2.1 CTU eTMF

All paper and electronic data including the eTMF and study data collection system(s) will be retained and archived in accordance with OCTRU's SOPs which are compliant with the UK GDPR.

37.2.2 eISF and participant medical records

The eISFs will be archived at the research site. The medical files of study participants must be retained for the mandatory archiving period stated above and in accordance with the maximum period of time permitted by the research site. Sites must comply with the documentation retention specified in the clinical trial agreements (or equivalent) issued by the study Sponsor.

38 DATA SHARING

38.1 Data sharing during the study

The data sharing arrangements during the study are detailed in a separate DMP. Data will be shared only with the appropriate consent from the study participant.

38.2 Data sharing at the end of the study

The study statistician, CI and health economist may retain copies of anonymised datasets for the purpose of data sharing in accordance with the study data sharing plan. Anonymised data may also be used for teaching and learning purposes.

Upon completion of the study, anonymised research data may be shared with other organisations upon request. All requests for data sharing will be handled in accordance with the OCTRU SOP on Data Sharing and will be considered in accordance with the data sharing policies of OCTRU, the Sponsor and funder.

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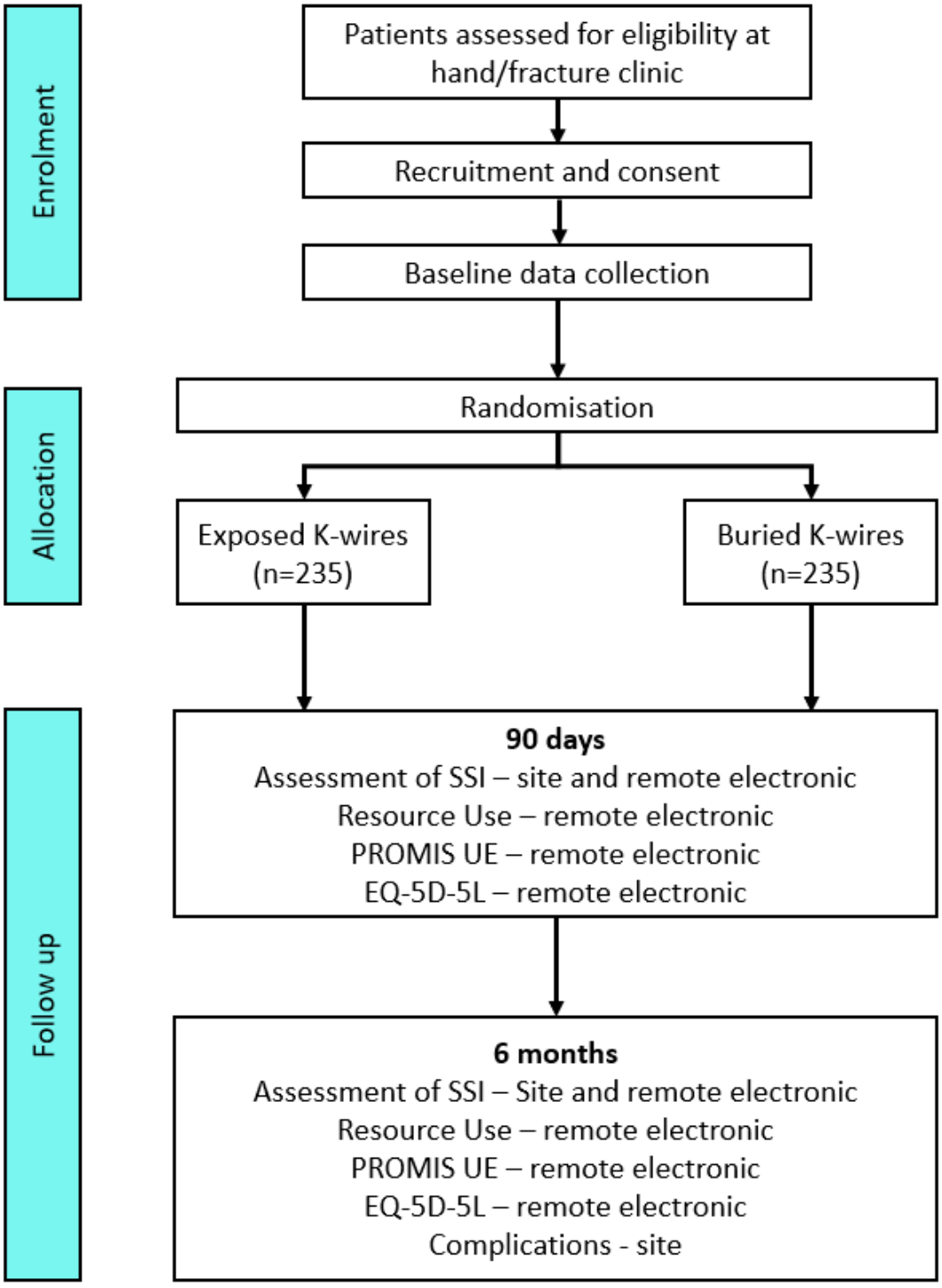
40 VERSION HISTORY

Previous versions of this protocol and a summary of the changes made are listed below.

Protocol version no.	Protocol date	Summary of key changes from previous version
1.0	23Oct2025	1st version of the protocol
2.0	11Mar2026	Inclusion criteria and section 13 study intervention updated for clarification. Section 24.5 Subgroup analysis minor update.

APPENDIX 1 – STUDY FLOW CHART



APPENDIX 2– DATA COLLECTION

Screening:

Sourced/Collected by Site Research Team (Screening Form)

- Participant Demographics
    - Date of injury
    - Age
    - Biological Sex
    - Ethnicity
    - Index of multiple deprivation
- Eligibility criteria
- Reasons for declining participation (e.g. treatment preference)
- Reasons for not recruiting (e.g. missed, administrative issues)

Contact Details:

Direct Participant Reported

- First name
- Surname
- NHS/CHI/H&C Number
- Date of Birth
- Contact details (Email address/mobile number/landline number)
- Postal address

Baseline:

Direct Participant Reported

Baseline Participant Form:

- Hand dominance
- Alcohol status
- Smoking status
- Diabetes status and medication
- Conditions or medication that reduce the immune system
- Work status

Other baseline forms:

- EQ-5D-5L (pre injury)
- EQ-5D-5L (post-injury)
- PROMIS Upper Extremity (pre injury)
- PROMIS Upper Extremity (post-injury)

Sourced/Collected by Site Research Team (Baseline Hospital Form)

- Height and weight (BMI calculation)
- Anatomical location of injury (hand/wrist)
- Open/closed fracture

Randomisation:

Sourced/Collected by Site Research Team (Randomisation Forms)

- Further eligibility assessment/exclusion reasons
- Site

Treatment:

Sourced/Collected by Site Research Team in post-operative period (Treatment Form)

- Wound contamination
- Other injured structures
- Initial management (antibiotic prescription, treatment, hospital stays)
- Visits between initial visit and surgery (as above)
- Date of surgery
- Treatment/allocation receipt
- Grade of most senior scrubbed person
- Surgical cleaning fluid and surgical preparation
- Injury details (fracture type, ray, bone)
- K Wire details (number of k wires, attempts at passing wire, crossing joints, planned removal)
- Hospital stays
- Surgical dressings and wound closure details
- Perioperative complications
- Perioperative and post-operative antibiotics
- PDF upload of operation notes

90 days:

Direct Participant Reported

Resource use:

- SSI (presence infection requiring prescription of antibiotics) – antibiotics details, who prescribed, length of prescription.
- Outpatient appointments (which department, treatment received)
- Inpatient stays (number of days, ICU/HDU number of days)
- Contacts with community professionals
- Contacts with private health services and cost
- Employment status (time off work)
- Use of personal social services (which service, number of times, duration)
- Help at home (how many days, hours per day)
- Use of aids and adaptations (how many, cost)

Other 90 day forms:

- EQ-5D-5L
- PROMIS Upper Extremity (Short form if paper questionnaire)

Sourced/Collected by Site Research Team (Site SSI)

- SSI (presence infection requiring prescription of antibiotics) – antibiotics details, who prescribed, length of prescription.

6 months:

Direct Participant Reported

- SSI and Resource use (as above)
- EQ-5D-5L
- PROMIS Upper extremity (Short form if paper questionnaire)

Sourced/Collected by Site Research Team

- SSI (As above)
- Medical Records check (Complications)
    - Wire loosening
    - Wire extrusion and unplanned removal
    - Wire loss/falling out
    - Wire breakage and removal/need for re-fixation
    - Scar related complications
    - Bone related complications
    - CRPS diagnosis
    - Further surgery (for infection, loss of fracture position/malunion, removal of symptomatic metalwork)
    - Details of further surgery (location, anaesthetic type, grade of most senior scrubbed person, surgical cleaning fluid and preparation, hospital stay, antibiotic prescription)
    - PDF Upload of further surgery operation notes