# Buried versus exposed wires in hand and wrist fractures

| Submission date   | Recruitment status       | [X] Prospectively registered    |
|-------------------|--------------------------|---------------------------------|
| 03/11/2025        | Not yet recruiting       | ☐ Protocol                      |
| Registration date | Overall study status     | Statistical analysis plan       |
| 11/11/2025        | Ongoing                  | Results                         |
| Last Edited       | Condition category       | Individual participant data     |
| 11/11/2025        | Musculoskeletal Diseases | [X] Record updated in last year |

#### Plain English summary of protocol

Background and study aims

Fractures of the bones of the hand and wrist are the most common subtype of hand trauma, accounting for about 50% of all injuries. Although most do not need surgery, a proportion will be unstable and will require manipulation and fixation with metalwork to restore hand function. Recent UK studies indicate that over 50,000 hand and wrist fractures are operated on per year in the NHS. 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. 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. 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. Acquiring an SSI doubles the length of hospital stay and leads to substantial additional direct healthcare costs.

#### Who can participate?

Adult participants, aged 16 or over, with fractures of the hand or wrist which require fixation with k-wires.

#### What does the study involve?

The aim of this study is 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. We will compare the risk of SSI by 90 days post-randomisation between treatment groups.

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.

If an individual wishes to join the study, a researcher will discuss the study with them, answer any questions they may have, and ask them to fill in a consent form. They will then answer some questions about themselves, their health, and their quality of life. There will also be questions that ask how well they could do everyday tasks before they broke their hand or wrist, and how well they can do those now. Completing these questions will take about 15 minutes. Similar questions will be asked during their recovery at 3 and 6 months.

To compare the treatments, participants will be put into two groups:

Exposed K-wires: The broken bones in the hand or wrist will be held in place by wires where the end of the k-wires is left sticking OUT of the skin. The 'exposed' part is short (about 2–3cm/1 inch), they might get stitches, and the exposed k-wire will be covered with a sterile dressing and usually a cast. The dressing/cast might be replaced after a few weeks. After about 6 weeks, they will come back to hospital where the k-wires will be removed during their usual follow-up hospital appointment.

Buried K-wires: The broken bones in the hand or wrist will be held in place by k-wires with the ends buried UNDER the skin. At the end of the operation, they will usually get stitches and a plaster cast. After some weeks, this cast will then get replaced with a brace/splint. They might need to come to hospital to have their wound/stitches checked. After about 6 weeks, they will come back to hospital where the k-wires will be removed, usually in an operating room. They will receive a local anaesthetic, and a small cut will be made in the skin to remove the k-wires.

#### What are the possible benefits and risks of participating?

There is no direct benefit in taking part in the study. The information we receive will help in improving care for patients in the future. We do not know whether there is a difference in recovery for patients who get buried or exposed k-wires. This is why we are doing this research. If you join in, it will help us make treatment better for future patients with similar injuries. This study will also help us find out if one treatment costs more than the other. This will allow the NHS to make a decision about how to best spend their funds.

The risks in this study are the same as standard care because both treatments are carried out in routine care. Although there is no additional risk in taking part, both treatments have disadvantages. For those patients where the k-wires are not buried under the skin, there might be a slightly higher risk of infection. On the contrary, patients with buried k-wires will have to return to hospital for a second operation to have the k-wires removed.

#### Where is the study run from?

The University of Oxford is sponsoring this study. This study will be overseen by Oxford Clinical Trials Research Unit (OCTRU) with the day to day running of the study being completed by Oxford Trauma and Emergency Care at the University of Oxford, led by Mr Justin Wormald, Chief Investigator and Clinical Lecturer.

When is the study starting and how long is it expected to run for?

The study enrolment is planned for January 2026, over approximately a 15 month period at least 22 UK hospitals.

#### Who is funding the study?

National Institute for Health and Care Research (NIHR) Research for Patient Benefit programme, UK.

Who is the main contact?
Mr Justin Wormald, HAWAII-DRIFT@ndorms.ox.ac.uk

## Contact information

#### Type(s)

Scientific, Principal investigator

#### Contact name

Mr Justin Wormald

#### **ORCID ID**

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#### Contact details

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## Additional identifiers

#### Clinical Trials Information System (CTIS)

Nil known

## Integrated Research Application System (IRAS)

IRAS 342133

## ClinicalTrials.gov (NCT)

Nil known

#### Protocol serial number

CPMS 61682, NIHR207194

## Study information

#### Scientific Title

Hand And Wrist: Antimicrobials and Infection – burieD vs. exposed K-wiRes In Fracture fixaTion

#### Acronym

**HAWAII DRIFT** 

#### **Study objectives**

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

#### Ethics approval required

Ethics approval required

#### Ethics approval(s)

submitted 24/10/2025, South Central Oxford B Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8032, (0)207 104 8243; oxfordb. rec@hra.nhs.uk), ref: 25/SC/0365

#### Study design

Randomized controlled trial

#### Primary study design

Interventional

#### Study type(s)

Treatment

#### Health condition(s) or problem(s) studied

Musculoskeletal

#### **Interventions**

This trial is a multi-centre, two-arm, parallel design, superiority, randomised controlled clinical study. Participants will be randomised to either buried K-wires or exposed K-wires for treatment of their hand or wrist fracture; the randomisation will be on a 1:1 basis, stratified by hand or wrist injury, research site and open or closed injury at presentation. A total of 470 participants will be recruited across a minimum of 22 research sites within the UK.

A member of the research team at each site will initially screen patients for eligibility upon their presentation to hand trauma clinics or fracture clinics. If eligibility is confirmed, a trained member of the research team will approach the patient to give them a participant information sheet (PIS) and to explain the study to them. If they wish to proceed with participation, they will provide informed consent.

Participants will then complete baseline questionnaires based on how they were feeling before their injury (answered retrospectively) and how they are feeling today on their presentation to the hand/fracture clinic.

When the participant returns to have their surgery, their eligibility for the study will be reassessed to check that they are still eligible (e.g. they haven't contracted a skin infection over the intended site of the wire placement). This could also mean that a patient who was previously ineligible for the study may become eligible at this point. For example, if a nonoperative approach was initially decided when the patient was first screened, but now they will be having surgery, they may be approached to take part in the study.

Once eligibility is confirmed, the participant will be randomised in the operating theatre, and subsequently followed up at 90 days and 6 months post-randomisation. Web-based randomisation will be used, 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).

Data will be collected via the clinical trial IT system REDCap, hosted by the University of Oxford, UK. Baseline demographic data will be entered directly by the site staff during the initial visit, and all baseline questionnaire data will be entered directly by the participant. Participants will then be contacted for follow-up using email and/or SMS text message prompts and invited to complete questionnaires through an online link. Telephone and postal follow-up will be conducted for those who require it. Follow-up will be conducted centrally by the trial team.

#### Intervention Type

Procedure/Surgery

#### Primary outcome(s)

The risk of surgical site infection (SSI) will be measured using patient- and site-reported prescription of antibiotics for the presence of an SSI using data collected from REDCap by 90 days post-randomisation

#### Key secondary outcome(s))

- 1. Upper extremity function and pain measured using PROMIS Upper Extremity at Baseline (preand post-injury), 90 days and 6 months
- 2. Health-Related Quality of Life will be measured using the EQ-5D-5L at Baseline (pre- and post-injury), 90 days and 6 months
- 3. Risk of complications will be measured using the site-reported complications at treatment and medical records check at 6 months
- 4. Assess costs and comparative cost-effectiveness will be measured using a bespoke participant resource use questionnaire at 90 days and 6 months

#### Completion date

28/02/2028

## Eligibility

#### Key inclusion criteria

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

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Mixed

#### Lower age limit

16 years

#### Upper age limit

100 years

#### Sex

All

#### Total final enrolment

0

#### Key exclusion criteria

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

#### Date of first enrolment

01/01/2026

#### Date of final enrolment

28/02/2027

## **Locations**

#### Countries of recruitment

**United Kingdom** 

England

## Study participating centre Royal United Hospital

Combe Park Bath England BA1 3NG

## Study participating centre Queen Elizabeth Hospital

Mindelsohn Way Edgbaston Birmingham England B15 2GW

#### Study participating centre

#### **Bradford Royal Infirmary**

Chesnut House Duckworth Lane Bradford England BD9 6RJ

## Study participating centre Stoke Mandeville Hospital

Mandeville Road Aylesbury England HP21 8AL

### Study participating centre St Thomas' Hospital

Westminster Bridge Road London England SE1 7EH

## Study participating centre Basingstoke and North Hampshire Hospital

Aldermaston Road Basingstoke England RG24 9NA

#### Study participating centre St Mary's Hospital

Praed Street London England W2 1NY

## Study participating centre St James' S University Hospital

Beckett Street Leeds England LS9 7TF

## Study participating centre Milton Keynes Hospital

Standing Way Eaglestone Milton Keynes England MK6 5LD

## Study participating centre Musgrove Park Hospital

Musgrove Park Hospital Taunton England TA1 5DA

#### Study participating centre Queens Medical Centre

Nottingham University Hospital Derby Road Nottingham England NG7 2UH

## Study participating centre John Radcliffe Hospital

Headley Way Headington Oxford England OX3 9DU

## Study participating centre Royal Cornwall Hospital

Treliske Truro England TR1 3LJ

## Study participating centre Salford Royal Hospital

Stott Lane Salford, Greater Manchester England M6 8HD

## Study participating centre King's Mill Hospital

Mansfield Road Sutton-in-ashfield England NG17 4JL

## Study participating centre St George's Hospital

Blackshaw Road Tooting London England SW17 0QT

## Study participating centre Wexham Park Hospital

Wexham Street Wexham Slough England SL2 4HL

## Study participating centre Whiston Hospital

St. Helens & Knowsley Hospital Warrington Road Prescot England L35 5DR

## Sponsor information

#### Organisation

University of Oxford

#### **ROR**

https://ror.org/052gg0110

## Funder(s)

#### Funder type

Government

#### **Funder Name**

National Institute for Health and Care Research

#### Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

#### **Funding Body Type**

Government organisation

#### **Funding Body Subtype**

National government

#### Location

United Kingdom

## **Results and Publications**

Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Data sharing statement to be made available at a later date

## **Study outputs**

Output type Details Date created Date added Peer reviewed? Patient-facing?

Participant information sheet
Participant information sheet
11/11/2025 No Yes