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Can we test antimicrobial stitches in surgery for hand and wrist injuries? A feasibility study

Submission date
31/01/2022

Recruitment status
No longer recruiting

Registration date
10/02/2022

Overall study status
Completed

Last Edited
28/09/2023

Condition category
Surgery

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Hand and wrist injuries, also known as hand and wrist 'trauma', account for 1 in 5 emergency hospital visits. Every year, over 5 million people in the UK are affected, from young working people to the elderly. The hand and wrist are important in daily life and for earning a living. Many injuries need surgery and there is a risk of infection afterwards. The risk is unknown, but it might be as high as 1 in 4 people. Also, little is known about the knock-on effects of infection, which might be severe, including amputation. At the end of surgery for these injuries, the skin is closed using stitches. Specially coated stitches, known as 'antimicrobial stitches', might reduce infection in the wound by killing nearby bacteria. Preventing infection after surgery could improve recovery, regaining hand and wrist function sooner, and could reduce NHS costs. We want to test the usefulness of these antimicrobial stitches with a clinical trial in the NHS. This small-scale study will look at antimicrobial stitches and infection. In this study, consenting participants with hand and wrist injuries from three hospitals in England will be allocated, by chance, into two groups. One group will get antimicrobial stitches during their surgery and one group will get normal stitches. There will be no other differences between the two groups. The purpose of this small-scale study is to test out the information we give to people and to see if people would be happy to take part. The practicalities of measuring infection after surgery will also be tested. The results will allow us to determine if we can conduct a larger study to see if the antimicrobial stitches do reduce infection in people having surgery for hand and wrist injuries.

Who can participate?
Adults 18 and older with injuries to the hand and/or wrist that requires surgery that involves stitching to repair the injury

What does the study involve?
Participants will either receive standard stitches or antimicrobial stitches, completely by chance. They will not know which ones they have received. Participants will be asked to fill in questionnaires before their operation, then at 30 days, 90 days and 6 months after their operation. All of the questionnaires are electronic and will be sent by email and/or SMS message. They can be completed on a computer, tablet or smartphone.

What are the possible benefits and risks of participating?
Participants will be contributing to our understanding of new technologies by engaging. This will help all patients in the NHS who need surgery. There are no significant risks that are directly related to the study. Some people may have a reaction to the material in the antimicrobial stitches, but this is extremely rare. Both types of stitches are currently in use in the NHS.

Where is the study run from?
The study is run from the Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences (NDORMS) at the University of Oxford (UK)

When is the study starting and how long is it expected to run for?
October 2020 to June 2023

Who is funding the study?
National Institute for Health Research (NIHR) (UK)
Royal College of Surgeons of England
The British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)

Who is the main contact?
Dr Justin Wormald, justin.wormald@sjc.ox.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
292544

Central Portfolio Management System (CPMS)
50951

National Institute for Health and Care Research (NIHR)
301793

Study information

Scientific Title
Hand and Wrist Trauma: Antimicrobials and Infection (HAWAII) Feasibility Study – A multi-centre feasibility study of antimicrobial sutures

Acronym
HAWAII

Study objectives
Is it possible to perform a randomised clinical trial of antimicrobial sutures versus standard sutures to determine whether they reduce risk of surgical site infection in adults after surgery for hand and wrist trauma?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 11/11/2021, South Central - Oxford C Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 207 104 8256; oxfordc.rec@hra.nhs.uk), ref: 21/SC/0334

Primary study design
Interventional

Study design
Interventional randomized controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Complications of surgical care following injuries to the wrist and hand

Interventions
Antimicrobial sutures.
Standard sutures.

Randomisation:
Those patients who consent to take part in the trial will have their treatment allocated using a secure, centralised, online randomisation service. Randomisation will be on a 1:1 basis, stratified by centre, and age of the patient and will be performed by the local clinical team immediately prior to wound closure.

Baseline data collection. The local clinical team or research nurse will enter baseline clinical information onto the CRF once a participant has been recruited. The participant will be asked to complete baseline questionnaires.

Follow-up: 30 days. Participants will receive an email/text invitation to complete the outcome measures at 30 days.
Follow-up: 90 days. Participants will receive an email/text invitation to complete the outcome measures at 90 days.
Follow-up: 6 months. Participants will receive an email/text invitation to complete the outcome measures at 6 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Measured using patient records at the end of the study:
1. Number of eligible patients that are randomised to either the intervention or control
2. Number of eligible patients
3. Number of patients that consent to be included in the study
4. Number of participants with completed outcome measures

Key secondary outcome(s)
1. Surgical site infection (SSI) measured using the Bluebelle Wound Healing Questionnaire (WHQ) at 30 days and 90 days post- surgery
2. Hand function measured using the Patient Evaluation Measure (PEM) Part 2 and PROMIS Upper Extremity (PROMIS UE) at 30 days, 90 days and 6 months post-surgery
3. Health-related quality of life (HRQoL)measured using the EQ-5D-5L at 30 days, 90 days and 6 months post-surgery
4. Return to work measured using a return to work questionnaire 90 days and 6 months post-surgery

Completion date
30/06/2023

Eligibility

Key inclusion criteria
Adults aged 18 years and above undergoing hand and wrist trauma surgery requiring sutures and able and willing to provide informed consent.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
116

Key exclusion criteria
1. Allergic to triclosan (active coating in antimicrobial sutures).
2. Infected wounds.
3. Wounds not amenable to skin closure with sutures.
4. Nailbed injuries.
5. Unable to complete study procedures, including the completion of a patient questionnaire in English.

Date of first enrolment
10/03/2022

Date of final enrolment
02/11/2022

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre
Amersham Hospital
Amersham Hospital
Whielden Street
Amersham
United Kingdom
HP7 0JD

Study participating centre
Treliske Hospital
Treliske

Truro
United Kingdom
TR1 3LJ

Sponsor information

Organisation
University of Oxford

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Government

Funder Name
NIHR Academy

Funder Name
Royal College of Surgeons of England

Alternative Name(s)
RCS England, RCS ENG, The Royal College of Surgeons of England, RCS

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
The British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)

Funder Name
National Institute for Health 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
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/09/2023	28/09/2023	Yes	No
Protocol article		01/07/2022	14/07/2022	Yes	No
HRA research summary			28/06/2023	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes