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PROTOCOL

Hand and Wrist Trauma: Antimicrobials and Infection (HAWAII)

A PROTOCOL FOR A MULTICENTRE, FEASIBILITY STUDY OF ANTIMICROBIAL SUTURES IN HAND AND WRIST TRAUMA SURGERY

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Aims

Hand trauma accounts for one in five of emergency department attendances, with a UK incidence of over five million injuries/year and 250,000 operations/year. Surgical site infection (SSI) in hand trauma surgery leads to further interventions, poor outcomes, and prolonged recovery, but has been poorly researched. Antimicrobial sutures have been recognized by both the World Health Organization and the National Institute for Clinical Excellence as potentially effective for reducing SSI. They have never been studied in hand trauma surgery: a completely different patient group and clinical pathway to previous randomized clinical trials (RCTs) of these sutures. Antimicrobial sutures are expensive, and further research in hand trauma is warranted before they become standard of care. The aim of this protocol is to conduct a feasibility study of antimicrobial sutures in patients undergoing hand trauma surgery to establish acceptability, compliance, and retention for a definitive trial.

Methods

A two-arm, multicentre feasibility RCT of 116 adult participants with hand and wrist injuries, randomized to either antimicrobial sutures or standard sutures. Study participants and outcome assessors will be blinded to treatment allocation. Outcome measures will be recorded at baseline (preoperatively), 30 days, 90 days, and six months, and will include SSI, patient-reported outcome measures, and return to work.

Conclusion

This will inform a definitive trial of antimicrobial sutures in the hand and wrist, and will help to inform future upper limb trauma trials. The results of this research will be shared with the medical community through high impact publication and presentation.

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Introduction

Hand trauma, comprising injuries to both the hand and wrist, affects over five million people per year in the NHS, and result in around 250,000 operations per year.[1] These figures are both increasing with time; as the UK population grows, the number of injuries and operations also increase.[2] Hand trauma comprises a significant emergency workload in the UK and in Europe, demonstrated by several epidemiological studies from the Netherlands,[3] Denmark,[4] and Scotland.[5] In these studies, ranging from 1985 to 2007, hand trauma consistently accounted for over one in four injuries requiring an emergency department (ED) attendance, and up to one in five of all-cause ED attendances.[4,5] The high incidence of hand trauma results in substantial costs to the health service. One of these studies costed, hand and wrist injuries cost £460 million in 2007 to 2008, which was more than hip fractures (£335 million) and head injury (£223 million). Direct healthcare costs accounted for 44% of this figure, with the remainder consisting of indirect productivity costs.[3] These indirect costs

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demonstrate that the majority of injuries occur in the young, working, male population (aged 24 to 64 years; 57% male), and that they lead to considerable disability and loss of earnings.[3]

Infection at the site of an operation, commonly known as a surgical site infection (SSI), is one of the most common healthcare associated infections worldwide.[6] The consequences of SSI following hand trauma surgery include increased antibiotic prescription, reoperation, hospital admission, delayed rehabilitation, and, in severe cases, loss of all or part of the affected limb.[7-9] Already incapacitated by the injury, SSI can further postpone or prohibit return to work and independent living. The combined effects of SSI after surgery increase both the direct and indirect socioeconomic costs to the patient, the health and care services, and the wider UK economy.[10] The National Institute for Health and Care Excellence (NICE) reports the UK incidence of SSI to be between 3% to 5% across all surgical procedures.[11] There is no reliable or contemporary data to inform the risk of SSI in hand trauma. However, the literature reports risks ranging from 5% to 10% in bony injuries and 5% to 13% in soft-tissue injuries, consistently higher than the NICE estimate.[7,12-14] The severity of hand and wrist SSI ranges from superficial infections requiring further antibiotics, deep infections requiring reoperation, life-threatening sepsis, toxic shock syndrome, and death.[15-18]

It is widely accepted that surgical suture material is a common source of bacterial wound infection.[19] Sutures coated in triclosan, an antimicrobial agent, can reduce SSI in major abdominal and vascular surgery procedures by around 28% (meta-analysis of 21 randomized controlled trials (RCTs)).[20] These 'antimicrobial sutures' are more expensive than standard sutures: approximately £10 more per suture pack (£14.80 vs £4.71). However, a recent economic evaluation of RCTs found antimicrobial sutures to be cost-effective in specific patient populations.[21] In these RCTs, the study populations are undergoing major, invasive surgery to the abdomen (e.g. laparotomy) with long operative times, adjunctive courses of intravenous antibiotics, and long inpatient hospital stays.[22-24] These study populations are not comparable to hand trauma patients and so the results are not generalizable. If antimicrobial sutures are effective in reducing hand trauma SSI, they could facilitate timely and more complete return of hand function. This would directly benefit patients in terms of earlier return to work and independent living, reducing the burden on the health service and economy. The first step in evaluating the effectiveness of antimicrobial sutures in hand trauma is a feasibility study. This will allow us to ascertain the feasibility of a large-scale definitive trial of this potentially beneficial intervention for hand trauma patients. In 2019, NICE recommended further research on 'which closure method or technique is the most effective for reducing SSI in patients undergoing emergency surgery?', recognizing that antimicrobial sutures have not been tested in many fields, including hand and wrist trauma surgery.[25] Furthermore, research into methods to prevent SSI was longlisted in the James Lind Alliance Priorities for Common Hand and Wrist Conditions.[26]

Therefore, we propose a multicentre, prospective feasibility RCT of antimicrobial sutures versus standard sutures for adult patients with hand and wrist trauma to prevent SSI.

Aims

The aim of this multicentre, randomized, feasibility RCT is to determine the key indicators of feasibility for a definitive trial of antimicrobial sutures versus standard sutures in hand and wrist trauma surgery.

Feasibility objectives. To establish key feasibility parameters to inform a definitive trial of antimicrobial sutures versus standard sutures in hand trauma surgery:

1. Number of eligible participants;
2. Number of participants that consent to be included in the study;
3. Number of eligible participants that are randomized to either the intervention or control; and
4. Number of participants with completed outcome measures at the set time points:

1. SSI recorded at 30 days;
2. SSI recorded at 90 days;
3. PROMs completed at 30 days;
4. PROMs completed at 90 days; and
5. PROMs completed at six months

6. The number of participants that suffer a complication.

The full trial objectives are:

1. To quantify differences in the rate of SSI in hand trauma surgery within 30 days and 90 days post-surgery between the treatment groups;
2. To quantify the differences in hand function at 30 days, 90 days, and six months post-surgery between the treatment groups;
3. To quantify differences in health-related quality-of-life (HRQoL) at 30 days, 90 days, and six months post-surgery between the treatment groups; and
4. To quantify the differences in costs and comparative cost-effectiveness between the treatment groups over the first six months post-surgery.

Study design. This multicentre, feasibility study will inform a definitive, large-scale RCT that will compare antimicrobial sutures versus standard sutures for prevention of SSI following surgery for hand trauma. The aim is to

determine key feasibility parameters for consent, recruitment, and compliance to inform a definitive trial.

When the participant attends the emergency clinic for assessment, they will be identified by the clinical team and approached by the research associate for consent and recruitment. The participants will be randomly assigned to either antimicrobial sutures or conventional sutures via a secure online randomization process following consent. Once they have been recruited, the research team will collect baseline demographic data and both pre-injury and post-injury functional data using the patient evaluation measure (PEM) and PROMIS Upper Extremity (PROMIS UE) patient-reported outcome measures (PROMs), as well as pre-injury HRQoL using the EuroQoL five-dimension five-level survery (EQ-5D-5L). When the participant attends for their operation, the research associate will collect and input operative data as per the operation note. Screening logs will be kept at each site to determine the number of patients assessed for eligibility and reasons for any exclusion. In addition, the number of eligible and recruited patients, and the number of patients who decline consent/withdraw, will be recorded.

During surgery, participants will receive either standard or antimicrobial sutures depending on their allocation. Both suture types are currently available on the shelf in operating theatres in the UK. The participant will be blinded to the allocation. Both before and after the suturing procedure, the participant will receive standard care for their injury as per the local hospital and NHS practice. Further follow-up after the operation will be as per usual clinical care at each site.

The participant will then be contacted by email or text at 30 days and asked to complete the next set of outcome measures, including identification of SSI. The same will then occur at 90 days. The participants will be contacted at six months and asked to complete PROMs and an employment questionnaire. Once these have been collected, follow-up will be complete.

Ethical approval. This study has been reviewed by the National Research Ethics Service Committee (21/SC/0334). The research will be carried out in compliance with the Helsinki Declaration.

Study registration. This study is registered with the International Standard Randomized Controlled Trial Number Register (ISRCTN10771059).

Study participants. Adults with hand and wrist injuries that require a surgical intervention that includes the use of surgical sutures.

Inclusion criteria. The inclusion criteria was adults (aged > 18 years) undergoing hand and wrist trauma surgery requiring sutures and providing informed consent.

Exclusion criteria. The exclusion criteria was:

1. Adults who were unable to give informed consent to participate;
2. Allergic to triclosan (active coating in antimicrobial sutures);
3. Adults with infected wounds;
4. Adults with wounds not amenable to closure with sutures;
5. Finger nailbed injuries; and
6. Adults who were unable to complete study procedures, including the completion of a patient questionnaire in English.

Recruitment. The study will be run across three centres for hand trauma in the UK: Oxford University Hospitals NHS Foundation Trust, Buckinghamshire Healthcare NHS Trust, and Royal Cornwall Hospitals NHS Trust.

Screening of potentially eligible participants will be performed by a member of the local clinical team, who will then alert the research team. All potentially eligible patients will be screened and assessed for eligibility for entry into the study by a member of the research team delegated to conduct screening. If an eligible participant is identified, then they will be approached by a trained member of the research team who will provide them with written study information to consider and then asked for their written informed consent. All written study information has been reviewed by the project-specific PPI group before trial commencement. Screening logs will be kept at each site to determine the number of patients assessed for eligibility and reasons for exclusion. In addition, the number of eligible and recruited patients, and the number of patients who decline consent or withdraw, will be recorded.

We commenced recruitment in March 2022, which will last for 12 weeks from site opening.

Consent. Once eligibility for the study has been confirmed, informed consent will be sought. In order to standardize the information provided to the patients, written recruitment materials will be made available to the research team at all sites. The potential participant will be given a participant information sheet (PIS) explaining the study and the study procedures. The research team will also be able to answer any additional questions that the patient might have. This will then lead on to an informed consent discussion. Patients will be given as much time as possible to consider the information and discuss it with relatives/carers. It will be clearly stated that the participant is free to withdraw from the study at any time for any reason without prejudice to future care, without affecting their legal rights, and with no obligation to give the reason for withdrawal.

Before any study-related procedures or data are collected, participants will complete the latest approved version of the consent form electronically. They will be asked to provide their contact details if they are willing to consent in order for an electronic copy of the form to be sent to them immediately. The person performing the

consent procedure must be suitably qualified and experienced, and have been authorized to do so by the principal investigator. The local research team will be able to download a copy to place in the participant's medical notes. If the participant does not have access to email, then a paper copy of their consent form will be provided by the local research team instead. The trial website will be maintained until the study archive period has reached completion.

Post-recruitment withdrawals and exclusions. During the course of the trial, a participant may choose to withdraw early from the study at any time, without giving reasons, and without prejudicing their clinical care. Participants will not have the option to withdraw the data collected up until the point of withdrawal, as the data will be required for the intention-to-treat analysis and safety analysis. The options for withdrawal will be explained clearly in the PIS. The type of withdrawal and reason for withdrawal, if the participant is willing to provide one, will be recorded in the withdrawal case report form (CRF).

Treatment allocation. Those patients who consent to take part in the trial will have their treatment allocated using a secure, centralized, online randomization service. All hospital treatment areas have access to online resources, and so will be able to access the randomization service in real time ensuring no delay in the treatment of the participant. The randomization service will be open 24 hours each day to facilitate the inclusion of all potentially eligible patients. Randomization will be on a 1:1 basis, stratified by age of the patient and whether the injury was open or closed. Stratification by age will be used to ensure that there are equivalent numbers of age groups in each treatment arm. Open soft-tissue trauma of the hand and wrist is more common in younger, working male populations, often sustained at work or during recreation, although its incidence is increasing in older populations too.[2] Closed fractures of the wrist are more common in older female patients, most often from a mechanical fall. Closed hand fractures occur in both age groups, increasingly so in the older population. As fracture of the distal radius is the most common age-related injury, the stratification will be above and below 50 years of age. A study by Court-Brown and Caeser[27] assessed over 1,000 patients with a fracture of the distal radius, confirming a bimodal distribution for this type of fracture according to the age of the patient. The crossover of the two peaks of incidence was around 50 years of age. These studies provide strong evidence that patients aged over 50 years become increasingly vulnerable to fragility fractures of the distal radius. Therefore, we have chosen an age ± 50 years as the stratification criteria for this trial.

Blinding. Participants will be blinded to the allocation of treatment. Outcome measurement will be completed remotely and electronically by the participants themselves. Therefore, outcome assessment will be blinded. If a procedure is performed under local anaesthetic, the operating teams will be briefed on not disclosing the allocation while the participant is able to hear, a method in use in another NIHR funded hand trauma.[28] Data analysis will be performed by the trial team.

Interventions

Antimicrobial sutures. The intervention will be antimicrobial sutures provided by Ethicon, USA (e.g. Monocryl Plus, PDS Plus). These are sutures coated in triclosan, which is a routinely used antimicrobial agent. The amount of triclosan required to convey an antimicrobial effect to a suture is extremely small in comparison to the amounts used in commercial and environmental products.[21] Although mild allergy can occur with triclosan, there have been no reports of any adverse reaction with antimicrobial sutures in the last 13 years.

Standard sutures. The control will be standard, non-antimicrobial sutures of any kind, as per standard practice at each site.

Other treatments. Participants will receive usual pre-, peri- and postoperative care according to site routine practice. Usual care data will be recorded and analyzed from a feasibility point of view.

Follow-up

Clinic visit. Participants will attend a routine follow-up visit to check wound healing, approximately one week after their injury depending on local clinical practice. During this visit, their dressing will be removed, the wound inspected, and swabbed if indicated. They will then usually be referred to hand therapy for rehabilitation. The local clinical will record any early complications that have occurred at this appointment.

Remote follow-up. Subsequent data collection will be via email and/or text link to the online questionnaires to be completed remotely. If the Bluebelle Wound Healing Questionnaire (WHQ),[29] a disease-specific PROM that has been developed using contemporary methods to detect presence of SSI in surgical wounds, identifies an SSI at 30 or 90 days, a review of the medical notes by the local PI team will be triggered, to confirm the presence of an SSI and its management. PROMs will be deployed electronically at baseline, 30 days, 90 days, and at six months as per the schedule below. If a participant is unable to complete the PROMs electronically (i.e. unable to type due to loss of hand/wrist function), then they will be offered an opportunity to complete them over the phone with a member of the research team.

Schedule. Baseline and pre-injury PROMs will be collected at recruitment. PROMs and the Bluebelle WHQ will be deployed at 30 days and 90 days. PROMs and an employment status questionnaire will be deployed at six months (see Supplementary figure a).

Outcomes

Primary outcomes. The primary outcomes for this study are measures of feasibility that will inform recruitment, compliance, and retention for a definitive study.

Secondary outcomes

Surgical site infection. We will use the Bluebelle WHQ to detect occurrence of SSI at 30 days and 90 days. It maps to the CDC definition of SSI and has been validated for use in UK populations and for completion by participant or observer.[30] If a participant's score on the Bluebelle WHQ indicates presence of an SSI (score > 5), this will trigger a medical notes review by the local PI team to confirm the presence of SSI.

Hand and wrist function. The PPI representatives strongly endorsed the use of PROMs to assess the patient-centred aspects of hand and wrist function in the feasibility study. We will use two PROMs to measure hand and wrist function: PEM and PROMIS UE.

The PEM part 2 is an established PROM for assessing hand function in clinical trials and has been in use since its development in 1995.[31] Despite some gaps in the evidence for its overall validity, it has been successfully used in previous National Institute for Health and Care Research (NIHR) studies.[32] The PEM consists of ten questions, addressing different aspects of hand function. Each question is scored using a seven-point scale, with 1 being the best and 7 being the worst. A lower score is therefore indicative of better function and symptoms and conversely a higher score indicates worse function.[31]

PROMIS UE is a contemporary PROM that measures upper limb function, developed using item response theory. It is being used in more recent NIHR-funded clinical trials in upper limb trauma, and correlates well with commonly used hand function PROMs.[33–35] PROMIS UE can be administered via a computer adaptive test (CAT) or a short form. With a CAT, participant responses guide the system's choice of subsequent items from the full item bank (165 items in total in adult bank). Although items differ across respondents taking CAT, scores are comparable across participants.[36] Where possible, we will use the CAT version. Items on the PROMIS UE have a five-point scale with 5 being the best and 1 being the worst. This means a higher score indicates better function and lower score indicates worse function.

Quality of life and return to work. We will collect the EQ-5D-5L, an established measure of HRQoL that is NICE recommended.[37–39] The EQ-5D-5L has five dimensions: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each dimension is then rated from 1 to 5, with 1 being the best score and 5 being the worst score: no problems, slight problems, moderate problems, severe problems and extreme problems. The scores for the five dimensions are then combined into a five-digit number that describes the patient's health state.[37] The EQ-5D-5L will be administered at baseline, 30 days, 90 days, and six months to capture changes in HRQoL. Employment status will be assessed at six months.

Power and sample size. A sample size of 116 is required to determine acceptable 95% confidence intervals (CIs) for participant compliance and retention, providing usable estimates for a definitive study. The 95% CI (Wilson's method) will have maximum CI width of 0.18 given 116 participants. The width could be as small as 0.12 (12%) depending upon the event proportion. We have conducted prior audit work that indicated a total of 58 potentially eligible patients per week across the three sites. Based on experience in previous hand and wrist trauma trials, 20% of this number will be successfully recruited (80% unwilling or not randomized/allocated).[40] This results in a conservative estimate of 12 recruited per week across all sites, requiring a recruitment period of 10 to 12 weeks.

Statistical analysis. We will perform descriptive summaries of the data both overall and also by treatment group (see Supplementary table i). No formal statistical comparison between groups is planned given the nature of the study. The number of eligible participants in total, the number of participants that consented for inclusion and the number of eligible participants randomized will be reported descriptively. The follow-up rates at each time point will also be reported. The proportion of participants randomized and those retained at six months will be reported with 95% CIs to inform a definitive study.

Study reporting. The full trial will be reported according to the CONsolidated Standards Of Reporting Trials (CONSORT) extension for randomized feasibility studies.[28] This protocol has been reported in accordance with the SPIRIT statement (see Supplementary table ii).[41]

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Supplementary material

Figure showing the Hand and Wrist Trauma: Antimicrobials and Infection (HAWAII) patient pathway, and tables showing the HAWAII statistical analysis plan, and the SPIRIT 2013 checklist.

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Ethical review statement:
- This study has been reviewed by the National Research Ethics Service Committee (21/SC/0334). The research will be carried out in compliance with the Helsinki Declaration.

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