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PANACHE: A Pilot randomised trial comparing two forms of Absorbable versus Non-Absorbable sutures for Carpal tunnel Hand surgEry

Submission date 09/06/2023	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 12/09/2023	**Overall study status** Completed	
Last Edited 22/07/2024	**Condition category** Surgery	

Plain English summary of protocol

Background and study aims
Surgeons who perform carpal tunnel operations use different types of sutures (stitches) to close the wound at the end of the operation. “Non-absorbable” sutures need to be removed, usually after about two weeks. Alternatively, two different types of “absorbable” sutures which do not need to be removed may be used, sutures that fall off by themselves or sutures that remain under the skin and are slowly absorbed by the body. Surgeons do not know which type of suture, if any, is best for patients. The study team would like to learn whether using “absorbable” or “non-absorbable” sutures leads to a better outcome from the operation. This will be investigated by performing a clinical trial – or study – in which the different types of sutures will be used and the different outcomes will be compared. To provide reliable answers, a study needs to be performed with a very large number of patients, which is complex and costly. To make sure that a large study of this kind is feasible (i.e. it can recruit and retain enough participants) and that it is performed correctly the study team undertaking this pilot study as a “test run” on a smaller number of patients. This pilot study will help ensure the larger trial is well-designed and has the best chance of success.

Who can participate?
Patients aged 18 years old and over who are already on the waiting list for carpal tunnel release surgery in one of the three participating hospitals

What does the study involve?
Around 150 participants in three NHS Scotland Health Boards will be randomised to compare three suture types (50 in each group).

What sutures are being compared?
The study will not be testing new sutures. It is comparing three sutures already in common use for carpal tunnel surgery:
1. A “non-absorbable” suture, which needs removal

2. An “absorbable” suture which falls off by itself after a short time
3. An “absorbable” suture which remains under the skin and is absorbed by the body over time

Before the surgery, the surgeon will explain the study and the consent process and will check that patients meet the criteria to be eligible to participate. If they are eligible, and they decide to participate, they will be asked to sign a copy of the PANACHE Study Consent Form. This is in addition to the medical consent form for your carpal tunnel surgery. Participants will be asked to complete some questionnaires about their hand, their symptoms, and their quality of life (as well as about the process of enrolling in the study).
After randomisation, carpal tunnel surgery will be carried out at the hospital as normal. The type of suture used to close the wound will have been decided at random between the three types of suture, instead of being chosen by the surgeon.

What happens after the surgery if I decide to participate?
At the time of the surgery, participants will receive a patient diary to record events weekly related to their recovery, from the day of their surgery up to 6 months afterwards. For example, the study team would like them to record if they go to see their doctor or nurse if they have a complication if they take antibiotics and the date when they return to work or to their usual hobbies. The completed diary will be returned after 6 months along with your completed follow-up questionnaires.

Participants will be reviewed in the clinic at the hospital about 2 weeks after surgery to check the wound and remove the sutures if this is needed. During the visit, they will be asked to complete some questionnaires which won’t take very long (less than 10 minutes). Participants will also be given three questionnaire packs to take home, along with pre-stamped and addressed envelopes, to be completed and mailed back to to the researchers at 6 weeks, 3 months, and 6 months after their operation. They will receive a reminder to complete their questionnaires via a text message when the time to do so comes. Participants will not need to attend additional appointments at the hospital.

What are the possible benefits and risks of participating?
All three types of sutures are widely used but at present, the study team do not know which, if any, is best for patients. There are no direct benefits to participants taking part in this study, but the results from this study might help to improve the healthcare of patients in the future.

Apart from the usual treatment following carpal tunnel release, participants will have to complete questionnaires on the day of surgery, at the 2 weeks wound check appointment, and at 6 weeks, 3 months and 6 months, and complete a weekly diary for 6 months after their surgery. Some people may find these extra questions tiring to complete and return. Each set of questionnaires will take up about 15 minutes.

Where is the study run from?
This study has been organised by investigators at NHS Lothian, NHS Fife, NHS Tayside, and the University of Edinburgh, coordinated by the Edinburgh Clinical Trial Unit and sponsored by NHS Lothian and The University of Edinburgh (UK)

Who is funding the study?
The Chief Scientist Office (Scotland) (UK)

When is the study starting and how long is it expected to run for?
November 2022 to February 2025

Who is the main contact?
Lynn Dinsmore (Trial Manager), PANACHE.trial@ed.ac.uk (UK)

Contact information

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Principal investigator

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Additional identifiers

Integrated Research Application System (IRAS)
323433

Central Portfolio Management System (CPMS)
57871

Protocol serial number
AC23019

Study information

Scientific Title
A Pilot randomised trial comparing two forms of Absorbable versus Non-Absorbable sutures for Carpal tunnel Hand surgEry

Acronym
PANACHE

Study objectives
To assess the feasibility of a definitive trial, in terms of recruitment, retention, and acceptability of the interventions and compliance with follow-up in a pilot, multicentre, three-arm RCT of three common absorbable and non-absorbable suture materials for wound closure after carpal tunnel repair (CTR) surgery in the NHS.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 17/05/2023, South East Scotland Research Ethics Committee 01 (01 2nd Floor, Waverley Gate 2-4 Waterloo Place, Edinburgh , EH1 3EG, United Kingdom; +44 (0)7814 764241; sandra.wyllie@nhslothian.scot.nhs.uk), ref: 23/SS/0054

Primary study design
Interventional

Study design
Three-arm pilot multicentre feasibility study

Study type(s)
Other

Health condition(s) or problem(s) studied
Carpal tunnel release surgery in patients with carpal tunnel syndrome

Interventions
This is a three-arm pilot multicentre study aimed at testing feasibility and informing the design of a future definitive trial comparing the outcomes of wound closure after carpal tunnel surgery (CTR) with absorbable versus non-absorbable sutures. The study is based in three NHS sites in Scotland where CTR surgery is routinely performed.

This pilot phase trial will run according to the protocol planned for the definitive trial to determine the recruitment rate, with the addition of qualitative data gathering on trial performance. This will be critical in deciding whether to proceed to the definitive trial and whether any adjustments to the main-phase trial protocol are needed before doing so.

The study will recruit 150 patients (50 patients in each of the three arms) across the three study sites over a 92-day enrolment period at each site.
Participants will be randomised to one of three methods of wound closure:
Arm 1: non-absorbable - interrupted extruding nylon sutures, or
Arm 2: absorbable 1 - interrupted subcutaneous polyglecaprone sutures, or
Arm 3: absorbable 2 - interrupted extruding polyglactin 910 sutures

Intervention Type
Procedure/Surgery

Primary outcome(s)
The proportion of randomised patients from those eligible and approached measured using the electronic screening log at the end of the 92-day recruitment window

Key secondary outcome(s)
1. Exclusion/inclusion rate measured using the SEAR (Screened, Eligible, Approached, Randomised) approach at 2 weeks follow up
2. Completion of follow-up/dropout rate (proportion completing follow-up at each time point at 2 and 6 weeks, and 3 and 6 months
3. Substitution of randomisation suture allocation, and completeness of data collection measured using the Boston Carpal Tunnel Questionnaire (BCTQ), the Patient and Observer Scar Assessment Scale, Patient Scale (POSAS 2.0), the Patient Events Questionnaire (PEQ), and the EuroQol health-related of life questionnaire (EQ-5D-5L) at 2 and 6 weeks, and 3 and 6 months

The following outcomes will be explored for the proposed definitive RCT:
1. Estimate of the effect of the suture types on wound healing measured using Southampton Wound Score at 2 weeks
2. Scar quality measured using the POSAS 2.0 questionnaire at the follow-up points at 2 and 6 weeks, and 3 and 6 months
3. Functional outcomes measured using BCTSQ at each follow-up
4. Time to return to work and other normal activities measured using a patient diary and the PEQ at 2 and 6 weeks, and 3 and 6 months
5. Health economics outcomes and Health-related Quality of Life measured using the EQ-5D-5L pre-surgery, 6 weeks, and 3 and 6 months
6. Healthcare resource use over the 6-month follow-up period measured using both self-report with a bespoke set of brief resource use questions in the patient questionnaire capturing NHS healthcare resource utilisation, in primary and secondary care (administered at 6 weeks, and 3 and 6 months) and from patient diaries (completed weekly). The resource use data collected in the pilot will allow the estimation of very exploratory and descriptive healthcare resource use costs associated with each of the three treatment arms to be calculated, and only to help inform

the design of the health economic analysis component of a future larger trial, and thus will not be an endpoint in their own right.

Completion date
28/02/2025

Eligibility

Key inclusion criteria
1. Any adult patient (18 years or older at the time of surgery)
2. Scheduled to undergo a primary CTR during the period of recruitment
3. CTR performed through a standard open approach procedure
4. Able and willing to give consent to surgical procedure and follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Total final enrolment
92

Key exclusion criteria
1. Patient unable to provide informed consent
2. Revision/repeat carpal tunnel surgery
3. Adoption of a surgical approach different from the standard open incision (including extended carpal tunnel incision)
4. Additional simultaneous procedure(s) to the same upper limb
5. CTR performed in the context of trauma (non-elective procedure)
6. Patient did not receive the pre-enrolment information pack on the RCT prior to surgery
7. Patient non-English speaker
8. Patient unable to fill in questionnaires
9. Patient expresses a strong preference for one type of suture over the others when the option of different sutures is explained

Date of first enrolment
16/10/2023

Date of final enrolment
30/04/2024

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
NHS Lothian
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
Accord (United Kingdom)

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Government

Funder Name
Chief Scientist Office

Alternative Name(s)
CSO

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically available repository, in the Edinburgh University DataStore, following the completion of analyses

IPD sharing plan summary
Stored in non-publicly available repository