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A comparison of surgical and non-surgical management of thumb osteoarthritis

Submission date
15/08/2024

Recruitment status
Recruiting

Registration date
29/08/2024

Overall study status
Ongoing

Last Edited
16/01/2025

Condition category
Musculoskeletal Diseases

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Several different treatments are available for clinicians to use with patients who have osteoarthritis in the base of their thumb. The SCOOTT study aims to find out if there is any difference in outcome for patients with base of thumb osteoarthritis by comparing three different treatments. The first treatment is non-surgical, it involves a specialist-enhanced hand therapist-led package. The second treatment is a trapeziectomy (surgical). The third treatment is a thumb joint replacement (surgical). It is unknown which of these treatments works best in improving patients' thumb base pain. This research study aims to find out which treatment is best.

Who can participate?
Adults with symptomatic base of the thumb osteoarthritis can take part in this study if their treating clinician thinks that any of the treatments available in this study would be suitable for them.

What does the study involve?
Taking part in the study means that the participants' treatment will be decided by a scientific process called randomisation. The process is commonly used in research to help us work out which treatment is best. Participants will receive either the ENGAGE package, a trapeziectomy or a thumb joint replacement. Participants will be asked to complete 8 questionnaires over 18 months to find out how they are doing. Some of these can be done at home, online or over the phone, and some of them will be part of a clinic appointment as they will also involve measurements such as thumb range of movement and grip strength. Participants will receive two £15 vouchers as a thank-you for completing follow-ups in the study. Participants might also be invited to interview with a researcher.

What are the possible benefits and risks of participating?
Treatment for the base of thumb osteoarthritis can only be improved with the help of patients. Taking part in this study means that you could help improve the care of future patients who need treatment for the base of thumb osteoarthritis. There is no increased risk to you by participating in the study. The NHS has treated patients with the treatments that are compared in this study. Participants will face the same surgical and anaesthetic risks (if they receive a

surgical treatment) and receive the same care as patients who have any of these treatments without taking part in the study.

Where is the study run from?
York Trials Unit at the University of York (UK) manages the day-to-day running of the study

When is the study starting and how long is it expected to run for?
January 2024 to December 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR) Health Technology Assessment Programme (HTA)

Who is the main contact?
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Contact information

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Scientific, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
336574

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
NIHR 154694, CPMS 64089, IRAS 336574

Study information

Scientific Title
Surgery versus Conservative OsteOarthritis of Thumb Trial (SCOOTT). An RCT to determine clinical and cost effectiveness of treating arthritis of the base of the thumb, with or without surgery, and to determine the clinical and cost effectiveness of trapeziectomy versus base of thumb joint replacement

Acronym
SCOOTT

Study objectives
1. There is no difference in the AUSCAN score at 12 months post-randomisation between adults (≥16 years old) with BTOA treated with surgery versus non-surgical management.
2. CMCJR is inferior to trapeziectomy for the treatment of BTOA in adult patients (≥16 years old) as measured by the AUSCAN score at 12 months post-randomisation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 29/08/2024, Wales Research Ethics Committee 2 Cardiff (Health and Care Research Wales, 5 Castlebridge, Cardiff, CF11 9AB, United Kingdom; -; wales.rec2@wales.nhs.uk), ref: 24/WA/0237

Study design
Randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Base of the thumb osteoarthritis

Interventions

This study is a randomised controlled trial which aims to recruit 656 adults with basal thumb osteoarthritis who have been referred to secondary care. Recruitment will take place over 2 years from approximately 20 NHS trusts across the UK. Participants will be randomised to one of three treatment options: (1) Trapeziectomy surgery, (2) Thumb joint replacement surgery, or (3) ENGAGE therapy package (non-surgical).

Recruitment:
The research team will work closely with the clinicians and research staff at each recruiting site to optimise the screening and recruitment procedures for their local circumstances. All members of staff involved in eligibility sign-off and the informed consent process (including surgeons) will have training in Good Clinical Practice (GCP) or study-specific training. The NIHR Associate Principal Investigator (API) scheme will be utilised at participating sites to involve aspiring researchers to co-ordinate study recruitment. The APIs will be trained in study processes and will be supervised by the PI at the site. Potential participants will be provided with information about the study including a patient information sheet (PIS) at the earliest possible opportunity following presentation.

Consent:
Consent will be recorded via paper consent forms, which will be uploaded onto the secure web-based data collection interface 'REDCap' once complete, or via participant e-consent directly within the REDCap system. Informed consent will be obtained by an authorised and trained member of the trust research team or clinical staff.

Baseline data collection:
Once participant eligibility has been confirmed and consent has been obtained, a baseline visit will be completed to collect all baseline data. The following measures will be collected at baseline:
• Demographic measures collected via patient self-report: ethnicity, education, employment status, housing/accommodation status.
• Questionnaire measures: Australian/ Canadian Osteoarthritis Hand Index (AUSCAN) questionnaire, PEM Score, EuroQol 5 dimensions (5L) score (EQ-5D-5L) and Patient satisfaction
• Physical measures: Total range of motion (radial and palmar abduction), Kapandji opposition score, Grip strength and Key pinch strength.
• Grade/severity of OA and condition history
• Date of birth

Randomisation:
Following the baseline assessment, randomisation will be undertaken by a member of the Trust' s research team using REDCap. The outcome of the allocation will be communicated to the participant where possible in person but may also be communicated via telephone or email. Follow-up data collection. Follow-up data collection will involve participants completing questionnaires (which can be done remotely), but for some time points, there will be physical measurements too which will require them to attend a clinic appointment. Follow-up time points will be 6, 12* and 18 months after the date of randomisation and Day of treatment*, 6 weeks*, 3 months, and 6 months* after the date of treatment. Those marked with an asterisk will be required to attend a clinic visit.

Qualitative interviews
There will be a nested qualitative interview study within the trial which will look at the experience and acceptability of the interventions. Approximately 10-15 participants from each

of the three treatment arms will be selected and approached for interview. In addition, interviews will be conducted with approximately 15-20 clinicians (hand surgeons/ hand therapists and occupational therapists). These will include those who were involved in the trial and also those who were outside of the trial delivery. Written or verbal consent will be taken for all interview participants prior to the start of each interview. Where verbal consent is taken, this will be recorded by the research team separately from the interview.

Patient and public involvement and engagement (PPIE)
The SCOOTT PPIE group have contributed to the design of the trial, the intervention components, participant-facing study documents and the ENGAGE intervention resources

Intervention Type
Procedure/Surgery

Primary outcome(s)
Pain is measured using the AUSCAN hand pain index at 12 months post-randomisation

Key secondary outcome(s))
1. Pain is measured using the AUSCAN hand pain index and the PSEQ-2 at baseline, day of surgery /therapy, 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months (PSEQ-2) and 18 months post randomisation
2. Hand function is measured using the AUSCAN hand function and stiffness index and the PEM score at baseline, day of surgery/therapy, 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months and 18 months post randomisation
3. Range of motion is measured using the Kapandji score and Goniometry at baseline, 6 weeks and 6 months post treatment and12 months post randomisation.
4. Grip and Pinch strength is measured using Jamar dynamometers at baseline, 6 months post treatment and 12 months post randomisation
5. Healthcare and broader resource implications and comparative cost-effectiveness are collected from participant self-reports and hospital-completed forms at baseline, 6 weeks, 3 months and 6 months post treatment and 6 months, 12 months and 18 months post randomisation.
6. Health-related quality of life is measured by EQ-5D-5L at baseline, day of surgery/therapy, 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months and 18 months post randomisation
7. Patient acceptability is measured by a global question at day of surgery/therapy, 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months and 18 months post randomisation as well as with qualitative interviews during the follow up period
8. Complications are measured by reporting of complications and adverse events at 6 weeks, 3 months and 6 months post treatment, 6 months, 12 months and 18 months post randomisation

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Aged 16 years old and over
2. Symptomatic basal thumb osteoarthritis

3. The treating clinician thinks the patient would benefit from surgical intervention
4. The patient is suitable for both types of surgery
5. Able to consent to a surgical procedure

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
16 years

Sex
All

Key exclusion criteria
1. Inflammatory arthritis
2. Current or past infection around the base of the thumb
3. Previous surgery on the affected thumb joint
4. Any comorbidity which precludes them from undergoing surgical intervention

Date of first enrolment
17/12/2024

Date of final enrolment
30/06/2028

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
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Study participating centre

Royal Derby Hospital
Uttoxeter Road
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Study participating centre
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OX3 9DU

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Study participating centre
Royal Liverpool University Hospital
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L7 8XP

Sponsor information

Organisation
South Tees Hospitals NHS Foundation Trust

ROR
https://ror.org/02js17r36

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study (fully anonymised) will be available upon request after the publication of the study results from Prof. Catherine Hewitt (catherine.hewitt@york.ac.uk). Requests for access to data will be reviewed by the co-Chief Investigators, study Sponsor and trial team. Participants will be informed that information collected about them may be shared anonymously with other researchers and will be asked to consent to this.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes