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Randomisation to end to side anterior interosseous nerve transfer in cubital tunnel syndrome

Submission date
10/05/2024

Recruitment status
Recruiting

Registration date
14/05/2024

Overall study status
Ongoing

Last Edited
27/01/2026

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
This feasibility study will help inform the design and sample size for a subsequent larger multi-centre study to understand whether adding a nerve transfer to patients undergoing surgery for cubital tunnel syndrome (CuTS) helps to improve muscle strength in the hand. This study will be a feasibility study to help inform study design and demonstrate patient willingness to be involved. It will also facilitate sample size calculation for the future study.

Who can participate?
Patients aged 18 years old and over with CuTS diagnosed on clinical examination intrinsic muscle weakness/wasting

What does the study involve?
The study is investigating whether a nerve transfer at the wrist improves the functional outcome of patients with CuTS if done at the same time as standard decompression.

What are the possible benefits and risks of participating?
All research participants will undergo a detailed and thorough consenting procedure to allow them to obtain detailed knowledge of their injury and the treatment options. All patients will receive an additional incision which will allow access to stimulate the nerve to get a better idea about the severity of their ulnar nerve function. Additionally, participants randomized to receive the additional nerve transfer will have the potential benefit of enhanced recovery time or allowance for return of function that would otherwise be less likely to return.

The addition of an anterior interosseous nerve transfer to cubital tunnel surgery for patients with severe CuTS is performed routinely by some surgeons, however, a well-designed larger study has not yet been published.

Any surgery holds potential risks, and given that this will require a second incision this will include standard risks such as wound infection, wound breakdown, unpredictable scaring, damage to structures and the need for further surgery. These risks will be detailed in the consent form and weighed against the benefits of the additional procedure.

Where is the study run from?
Queen Elizabeth Hospital Birmingham, part of University Hospitals Birmingham NHS Foundation Trust

When is the study starting and how long is it expected to run for?
November 2022 to May 2026

Who is funding the study?
1. National Institute for Health and Care Research (NIHR)
2. The Pump Priming Fund of the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS)
3. The protocol was developed with a small grant from the University of Birmingham

Who is the main contact?
Mr Chris McGhee (Hands, Plastics and Peripheral Nerve Research Manager, University Hospitals Birmingham NHS Foundation Trust), Christopher.McGhee@uhb.nhs.uk

Contact information

Type(s)
Public

Contact name
Mr Christopher McGhee

Contact details
HaPPeN Portfolio Research Manager, Office 3, Level 4, Institute of Translational Medicine, Heritage Building, Queen Elizabeth Hospital Birmingham
Birmingham
United Kingdom
B152TH
+44 (0)121 371 8102
christopher.mcghee@uhb.nhs.uk

Type(s)
Principal investigator

Contact name
Mr Dominic Power

ORCID ID
https://orcid.org/0000-0003-1600-6418

Contact details
University Hospitals Birmingham NHS Foundation Trust, Office 3, 4th Floor Institute of Translational Medicine, Mindelsohn Way

Birmingham
United Kingdom
B15 2TH
+44 (0)1213718102
Dominic.Power@uhb.nhs.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
311475

Protocol serial number
CPMS 60556, 2171PT, IRAS 311475

Study information

Scientific Title
A randomised controlled trial of end-to-side anterior interosseous nerve transfer augmentation of ulnar nerve function in moderate and severe cubital tunnel syndrome

Acronym
REACTS

Study objectives
Cubital tunnel syndrome (CuTS) presents a significant physical and psychosocial burden with the majority of the afflicted patients of working age at the time of primary surgical decompression. The key objectives of surgery for CuTS are successful resolution of symptoms, rapid recovery, restoration of function and return to work, especially with advanced disease. The principal aim of this study is to demonstrate the feasibility of delivering a randomised controlled trial exploring end-to-side anterior interosseous nerve transfer augmentation of ulnar nerve function in moderate and severe CuTS.

This will:
- Explore the clinician’s willingness to recruit and randomise their patients to the study
- Explore the patient’s understanding and willingness to partake in the study
- Provide statistically relevant data in determining the responsiveness of the PRUNE score in this specific cohort of patients and surgical technique

Primary Objectives
- To measure functional recovery using the PRUNE score in the control and intervention groups

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 20/03/2024, West Midlands – Black Country Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8010; Blackcountry.rec@hra.nhs.uk), ref: 24/WM/0013

Study design
Feasibility randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Nerve transfer to patients having surgery for cubital tunnel syndrome

Interventions
The primary objective of the REACTs study is to understand the willingness of participants to participate in a randomised intervention for end-to-side nerve transfer following ulnar nerve decompression.

The primary outcome measure for the study is the Patient Reported Ulnar Nerve Evaluation (PRUNE) score measured at 12 months. The PRUNE was selected to assist in the power and sample size calculations for a larger randomised controlled trial into this intervention. The study will therefore recruit 20 participants who fulfil the criteria to undergo ulnar nerve decompression. The study will randomise participants on a 1:1 basis via a REDCap system to either:
- Ulnar Nerve Decompression only (Control Arm)
OR
- Ulnar Nerve Decompression with Distal Anterior Interosseous Nerve (AIN) transfer (Intervention Arm).

Potential participants will be screened from both new referrals to the Peripheral Nerve Service and from existing waiting lists. They will then be approached in the clinic by a study investigator or by a member of the research team. Patients who fulfil the inclusion criteria and are willing to provide written informed consent in line with the principles of Good Clinical Practice (GCP), will be randomised to either the Control or Intervention arm of the study. They will be aware of the voluntary nature of research and informed of their option to withdraw at any time. Participants will be blinded to their treatment allocation. To maintain this blinding, a small incision will be made, and the anterior interosseous nerve (AIN) stimulated intraoperatively in the Control arm to mimic the AIN transfer. The research team and operating surgeon will be unblinded and will not complete outcome assessments for patients. Outcome assessments will be completed by a blinded, experienced Hands Therapist. Unblinding will be permitted following study discontinuation, follow-up completion or to aid in assessment of Serious Adverse Events in the context of safety reporting. Blinding has been proposed as a means of reducing the bias from both patients and researchers. This was discussed with PPI members who were in agreement.

Patients will be followed up at Baseline, 2 Weeks, 3 Months, 6 Months and 12 Months.
The Baseline, 3 Month and 12 Month follow-up will occur in the clinic and will consist of the following:

- Sensory Assessment – utilising Semmes Weinstein Monofilament threshold testing
- Motor Assessment – Medical Research Council grading for motor function of target muscles, alongside:
o Key Pinch testing
o Tripod Pinch testing
o Grip Strength testing using Jamar Level II
- Patient Reported Outcome Measures:
o Patient Reported Ulnar Nerve Evaluation (PRUNE) Score
o Quality of Life Assessment using the EQ-5D-5L
o Pain Assessment using the Numerical Rating Scale (NRS).
- Complication rates assessed via:
o Wilson-Krout Criteria Outcome Measures
o Presence of Complication

The 2-week follow-up will occur alongside the participant's first dressings clinic appointment performed as routine clinical care and assess for the presence of complications only. The 6-month follow-up will collect only the Patient Reported Outcome Measures and this will be done remotely. An optional 24-month follow-up will be offered to patients, collecting only Patient Reported Outcome Measures to track the progression of change in patient symptoms. This data will be reported in a supplementary report after the final trial report.

The follow-up schedule and outcomes collected have been selected following discussion and review by a PPI panel. As the study is a feasibility trial, it will inform the design and sample size calculation for a future multicentre RCT. Analyses will be carried out to understand the cost-effectiveness of trial intervention through the collection of data on surgery duration.

Recruitment of patients will occur over 8-12 months, ending after the recruitment of the 20th participant. Follow-up will cease 12 months after final patient recruitment. Data analysis and write-up will be performed over 3 months and therefore the total duration of the study is anticipated to be between 24-27 months.

Patients will be asked if they wish to receive copies of the trial results following publication and a lay summary, infographics and any published material will be widely shared on social media.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Functional recovery measured using the Patient-Reported Ulnar Nerve Evaluation (PRUNE) score at 12 months

Key secondary outcome(s))
The following secondary outcome measures will be assessed at baseline, 3 months and 12 months:
1. Sensory assessment measured using Semmes-Weinstein Monofilaments threshold testing
2. Motor Assessment measured using the Medical Research Council grading for motor function of target muscles, alongside:
2.1. Key Pinch testing in kilograms
2.2. Tripod Pinch testing in kilograms
2.3. Grip strength testing using the Jamar Level II
3. Patient-reported quality of life measured using:

3.1. Patient-Reported Ulnar Nerve Evaluation (PRUNE) score
3.2. Euroqol EQ5D-5L for quality of life assessment
3.3. Numerical Rating Scale (NRS) for pain
4. Complication rates measured using:
4.1. Wilson-Krout Criteria Outcome Measures
4.2. Presence of Complications

At 6 months:
Patient-reported outcome measures will be collected only

Completion date
01/05/2026

Eligibility

Key inclusion criteria
1. Male or female patients aged 18 years old
2. CuTS diagnosed on clinical examination
3. Neurophysiology grade Moderate or Severe (as per the Padua classification)
4. Intrinsic muscle paralysis
OR
5. Intrinsic muscle weakness/wasting
6. EMG confirmation of UN innervated intrinsic hand muscle denervation (partial/complete)
7. Willingness to be randomised
8. Able to complete the follow-up pathway

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
100 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Inability to provide informed consent due to fluctuating or non-transient impairment of the mind

2. Patients in police custody
3. Known peripheral neuropathy
4. Current pregnancy
5. Patients with a history of other neuropathy which could affect the AIN function
6. Patients without a functioning Pronator Teres muscle

Date of first enrolment
01/05/2024

Date of final enrolment
01/05/2026

Locations

Countries of recruitment
United Kingdom

Study participating centre
Queen Elizabeth Hospital
Mindelsohn Way
Birmingham
England
B15 2TH

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust

ROR
https://ror.org/014ja3n03

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

Funder Name
University of Birmingham

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Funder Name
British Association of Plastic, Reconstructive and Aesthetic Surgeons

Alternative Name(s)
BAPRAS

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

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?
Protocol article		26/01/2026	27/01/2026	Yes	No