

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

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|--------------------------|-----------------------------|---|
| <b>Submission date</b>   | <b>Recruitment status</b>   | <input type="checkbox"/> Prospectively registered               |
| 10/05/2024               | Recruiting                  | <input checked="" type="checkbox"/> Protocol                    |
| <b>Registration date</b> | <b>Overall study status</b> | <input type="checkbox"/> Statistical analysis plan              |
| 14/05/2024               | Ongoing                     | <input type="checkbox"/> Results                                |
| <b>Last Edited</b>       | <b>Condition category</b>   | <input type="checkbox"/> Individual participant data            |
| 27/01/2026               | Musculoskeletal Diseases    | <input checked="" type="checkbox"/> 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 scarring, 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

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

311475

### ClinicalTrials.gov (NCT)

Nil known

### 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? |
|----------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Protocol article</a> |         | 26/01/2026   | 27/01/2026 | Yes            | No              |