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Comparing endoscopic decompression of the ulnar nerve with open decompression in the surgical management of cubital tunnel syndrome

Submission date
13/12/2023

Recruitment status
Recruiting

Registration date
28/02/2024

Overall study status
Ongoing

Last Edited
16/06/2025

Condition category
Surgery

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

Plain English summary of protocol

Background and study aims
Cubital tunnel syndrome is when a nerve is squashed at the elbow causing tingling and numbness in the hand, clumsiness of fine finger movements and loss of grip strength. Persisting symptoms can be treated with decompression surgery to release tight structures lying over the nerve.
There are two ways of performing decompression, one with open surgery where a cut is made in the skin along the course of the nerve, the other by keyhole surgery (endoscopic), with a small cut and using a camera to help see the nerve.
There are potential advantages and disadvantages of both techniques. After release, if the nerve moves excessively as the elbow bends the surgeon may need to correct the movement. This is easier with an open technique, but the extra scar from open surgery may cause symptoms to return. The keyhole surgery uses a smaller incision which may allow patients to recovery more quickly but is not currently performed regularly by UK surgeons.

To help design the best study we conducted a national survey of specialist surgeons who treat this condition and consulted researchers, statisticians, health economists and patients treated for cubital tunnel syndrome. A group of patients who have had treatment for cubital tunnel have agreed to be part of the patient and public advisory group (PPAG). They have helped design the study to make it easy for patients to take part with little burden. They have reviewed the selected outcomes measures and agreed that the PRUNE (Patient Reported Ulnar Nerve Evaluation) score is simple to complete and relevant to their symptoms. The patient group will continue to support all stages of the study. We have a patient representative as part of the study team.
The results of this study will provide evidence to guide future decision making for patients and clinicians in the treatment of cubital tunnel syndrome. We will publicise the study results widely to ensure they will be available to patients, the public, clinicians, healthcare managers and commissioners of treatment in the NHS.

Who can participate?
Patients aged 18 - 80 years with cubital tunnel syndrome and willing to undergo surgical treatment

What does the study involve?
The study will involve two phases. During the first phase surgeons will be trained to do the endoscopic surgery and information will be collected to help understand how quickly they learn the new skill and how well patients recover from surgery. The second phase involves conducting a study to compare the open and endoscopic operations using a randomised controlled trial. Patients agreeing to the study will be assigned at random to one of the two techniques (open or endoscopic). Information about their condition and recovery will be collected before and after surgery for a period of 6 months; 334 patients will be included from hospitals across the UK.

What are the possible benefits and risks of participating?
We hope that the information from this study will give the NHS a clear answer to the question of which surgery is best to treat individuals with Cubital Tunnel Syndrome (CuTS). We cannot promise that the study will help the recruited patients directly, but the information we receive has the potential to benefit all those with CuTS in the future. The procedures are already performed within the NHS and the surgeon has been fully trained to perform the operation. People sometimes feel uncomfortable answering certain questions about their health, or may feel unable to answer certain questions.

Where is the study run from?
University Hospitals Birmingham NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2023 to June 2027

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

Who is the main contact?
understudy@ndorms.ox.ac.uk
Dominic Power, dominic.power@uhb.nhs.uk

Study website
https://under.octru.ox.ac.uk

Contact information

Type(s)
Scientific, Principal Investigator

Contact name
Mr Dominic Power

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

Contact details

University Hospitals Birmingham NHS Foundation Trust
6th Floor, Nuffield House, Queen Elizabeth Hospital
Mindelsohn Way, Edgbaston
Birmingham
United Kingdom
B15 2WB
+44 121 371 2000
dominic.power@uhb.nhs.uk

Type(s)
Public

Contact name
Dr Scott Parsons

ORCID ID
https://orcid.org/0000-0001-9443-0543

Contact details
Surgical Intervention Trials Unit (SITU)
Nuffield Department of Orthopaedics Rheumatology and Musculoskeletal Sciences
University of Oxford
Botnar Research Centre
Windmill Road
Oxford
United Kingdom
OX3 7LD
+44 1865 223489
understudy@ndorms.ox.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
324952

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 324952, NIHR135260, CPMS 60315

Study information

Scientific Title
UNDER Study: Ulnar Nerve Decompression Endoscopic Randomisation Study. A prospective randomised controlled trial comparing endoscopic decompression of the ulnar nerve with open decompression in the surgical management of cubital tunnel syndrome

Acronym
UNDER Study

Study objectives
The aim of the UNDER Study is to train surgeons in the endoscopic cubital tunnel decompression technique and then to conduct a RCT comparing endoscopic and open decompression techniques in the surgical management of primary cubital tunnel syndrome

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 29/01/2024, West Midlands - Solihull Research Ethics Committee (Equinox house, City Link, East Midlands REC Centre, Solihull, NG2 4LA, United Kingdom; +44 207 104 8134; solihull.rec@hra.nhs.uk), ref: 24/WM/0002

Study design
Multicentre single-arm methodological cohort study followed by multicentre two-arm parallel-group superiority randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
See study outputs table

Health condition(s) or problem(s) studied
Cubital tunnel syndrome

Interventions
Participants will be recruited into UNDER Study at treating hospitals and will do so at either the Cohort or RCT phase. Participants in the Cohort will receive only Endoscopic Decompression surgery for their Cubital Tunnel Syndrome.

Those recruited to the RCT will be randomised to either Open or Endoscopic Decompression. Surgeons will initially recruit to the Cohort phase but will transition to the RCT phase upon completion of 3-5 decompressions and after undergoing a review by the Chief Investigator. The research team at the hospital will use a computer system to randomly allocate the participant to either Open or Endoscopic decompression. The randomisation may be performed before or on the day of surgery. The surgery will be completed in a day and the participant will receive the standard local post-surgery usual care from the hospital.

The patient will have one or two clinical follow-ups, 6-weeks (for Cohort only) and one at 3-months. In addition, all participants will receive follow-up questionnaires at 3-, and 6-months. If the participant receives their surgery more than 2 years before the end of trial data collection, they will also receive a 24-month follow-up questionnaire.

Intervention Type
Procedure/Surgery

Primary outcome measure
Phase 1: Surgeon Review CRF based on complications during and 6-weeks post-surgery, conversions to open decompression, and surgeon confidence from delivering the endoscopic decompression
Phase 2: Patient-rated ulnar nerve evaluation (PRUNE) score at 3 months post-surgery

Secondary outcome measures
1. Determine the cost effectiveness of ED and OD for the surgical management of CuTS using a parallel economic evaluation: Length of procedures recorded on day of surgery
2. Complications at all visits
3. EuroQol EQ-5D-5L measured at baseline, 3 months, and 6 months post-surgery (plus additional 24-month follow-up for those that reach this timepoint within the open data collection window of the study), Within-trial estimate of cost-effectiveness over a 6-month time horizon. Decision-analytic modelling-based estimate of cost-effectiveness over a lifetime time horizon
3. To assess the complication profile and rate for ED and OD techniques in the surgical management of CuTS:: Complications data captured and classified using the Clavien-Dindo system on day of surgery, 6-weeks (Phase 1 only), 3-, 6-, and 24-months
4. To assess clinical recovery in terms of elbow range of motion, muscle strength and return to work following ED and OD: Elbow goniometry plus BMRC motor function at baseline and 3-months, and work status at 3-, 6-, and 24-months
5. To assess clinical recovery in terms of function, symptoms, and pain: Modified Wilson Krout Classification at 6-Weeks (Phase 1 only), and three months
6. To assess patient satisfaction with the surgical scar for the ED and OD surgery: POSAS V2.0 at 3-months
7. To understand the surgeon learning curve for the ED procedure (Phase 1 & 2): Surgeon Confidence on day of surgery (Phase 1 only), Complications at 6 weeks (Phase 1 only), complications, revision rates and functional outcomes at 3-, 6- and 24-months
8. To determine symptom recurrence at 6 months following ED and OD: PRUNE score and need for secondary intervention at 6-months

Overall study start date
01/01/2023

Completion date
30/06/2027

Eligibility

Key inclusion criteria
1. Adult patients aged 18-80 years at the time of surgery
2. Clinical and neurophysiological diagnosis of cubital tunnel syndrome (CuTS) [moderate / severe CuTS with subjective or objective motor weakness]

or persistent symptoms of CuTS after a 3-month period of activity modification for mild severity cases
3. Patients willing to be randomised to either Endoscopic Decompression or Open Decompression surgery for CuTS*
*inclusion criteria for the RCT only

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
Up to 150 in Phase 1 and 334 in Phase 2

Key exclusion criteria
1. Patients with a previous surgery for CuTS in the same limb
2. Pre-operative ulnar nerve subluxation at the elbow identified on clinical examination
3. Clinical diagnosis of CuTS with normal neurophysiology studies
4. Planned concomitant surgery in the same arm
5. Patients unable to provide consent
6. Patients unable to complete the follow up pathway including completing follow-up questionnaires

Date of first enrolment
11/04/2024

Date of final enrolment
30/04/2026

Locations

Countries of recruitment
England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Study participating centre
University Hospitals Coventry and Warwickshire NHS Trust
University Hospital Coventry
Clifford Bridge Road
Coventry
United Kingdom
CV2 2DX

Study participating centre
Northern Care Alliance NHS Foundation Trust
Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Royal Devon and Exeter Hospital
Royal Devon & Exeter Hospital
Barrack Road
Exeter
United Kingdom
EX2 5DW

Sponsor information

Organisation
University Hospitals Birmingham NHS Foundation Trust

Sponsor details
R&D Office, 1st Floor Institute of Translational Medicine
Heritage Building. Queen Elizabeth Hospital, Edgbaston
Birmingham
England
United Kingdom
B15 2WG
+44 121 371 4185
r&d@uhb.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.uhb.nhs.uk/

ROR
https://ror.org/014ja3n03

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

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

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study protocol will be published in an open-access peer-reviewed journal in accordance with the Standard Protocol Items: Recommendations for Interventional Trials statement (SPIRIT, www.spirit-statement.org/). The study results will be published in an open-access journal, in

accordance with the NIHR's policy on open-access research. The study will be reported following the Consolidated Standards of Reporting Trials guideline (CONSORT) including any applicable extensions to this. The Template for Intervention Description and Replication (TIDieR) statement will be used for reporting the intervention.

Intention to publish date
30/06/2027

Individual participant data (IPD) sharing plan
Upon completion of the trial, and with appropriate participant consent, anonymised research data may be shared with other organisations on request to the Chief Investigator and in accordance with the data sharing policies of OCTRU, the Sponsor and funder.
Summary results data will be available on the trial registration database within 6 months of the end of the trial. Requests for data (anonymised trial participant level data) will only be provided at the end of the trial to external researchers who provide a methodologically sound proposal to the trial team (and who will be required to sign a data sharing access agreement with the Sponsor) and in accordance with the NIHR guidance. After the end of the study an anonymised study dataset will be created and stored for as long as it is useful, and may be shared with other researchers upon request). Participant consent for this is included in the informed consent form for the study.
Contact: understudy@ndorms.ox.ac.uk

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Cohort study version 2.0	24/01/2024	15/03/2024	No	Yes
Participant information sheet	RCT version 2.0	24/01/2024	15/03/2024	No	Yes
Participant information sheet	Cohort study version 3.0	24/10/2024	16/12/2024	No	Yes
Participant information sheet	RCT version 3.0	24/10/2024	16/12/2024	No	Yes