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Comparing the effectiveness of two treatments for severe cubital tunnel syndrome

Submission date
23/11/2019

Recruitment status
No longer recruiting

Registration date
04/07/2020

Overall study status
Completed

Last Edited
17/03/2022

Condition category
Nervous System Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Cubital Tunnel Syndrome is a condition that involves pressure or stretching of the ulnar nerve (also known as the “funny bone” nerve), which can cause numbness or tingling in the ring and small fingers, pain in the forearm, and/or weakness in the hand. Surgery may be needed to relieve the pressure on the nerve. This can involve releasing the nerve, moving the nerve to the front of the elbow, and/or removing a part of the bone.
Supercharged end-to-side nerve transfer for severe cubital tunnel syndrome is a recently developed technique which involves attachment of an additional nerve to the damaged nerve in order to speed up recovery of the damaged nerve.

Who can participate?
Patients aged 18 years or above with severe cubital tunnel syndrome.

What does the study involve?
Participants will be randomly allocated to receive standard treatment or standard treatment with additional nerve attachment (supercharged end-to-side nerve transfer). Patients will be followed up for two years.

What are the possible benefits and risks of participating?
Benefits: Each participant was given a free electromyographic examination
Risks: The experimental group had one more incision

Where is the study run from?
Third Hospital of Hebei Medical University, China

When is the study starting and how long is it expected to run for?
January 2013 to October 2017

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
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Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
THHMU20130178

Study information

Scientific Title
Conventional ulnar nerve decompression and transposition adding supercharged end-to-side pronator quadratus motor branch to motor branch of ulnar nerve transfer vs conventional ulnar nerve decompression and transposition alone for the treatment of advanced cubital tunnel syndrome: a comparison study

Acronym
SEPQMBMBUNT

Study objectives
The hypothesis is that the efficiency of ulnar nerve decompression and transposition is improved by adding the supercharged end-to-side pronator quadratus motor branch to motor branch of ulnar nerve transfer (SEPQMBMBUNT) in patients with advanced cubital tunnel syndrome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 01/02/2013, Institutional Review Board of the Third Hospital of Hebei Medical University (Ziqiang Road, Shijiazhuang, Hebei, 050051, China; +86 (0)31188603632; no email provided), ref: 20190391

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Advanced cubital tunnel syndrome

Interventions
Patients will be blinded and randomly allocated to the study group and control group. Patients in the study group will undergo the conventional ulnar nerve decompression and transposition adding supercharged end-to-side pronator quadratus motor branch to motor branch of ulnar nerve transfer. Patients in the control group will undergo conventional ulnar nerve decompression and transposition alone. Final assessments include pinch strength, 2-point discrimination of the little finger, and Disabilities of the Arm, Shoulder, and Hand Questionnaire.

Patients remained in hospital for 2 weeks and were followed up for 24 months.

Intervention Type
Procedure/Surgery

Primary outcome measure
Grip strength using a Jamar dynamometer (Sammons Preston Rolyan, Bolingbrook, Illinois), key pinch strength using a pinch gauge (B&L Engineering, Santa Ana, California), and tripod pinch strength (Baseline Hydraulic Pinch Meter, Fabrication Enterprises Inc., Irvington, NY, USA) at baseline and two years

Secondary outcome measures

1. 2-point discrimination of the little finger measured using Disk-Criminator (MackinnonDellon Partnership, Baltimore, MD) at baseline and two years
2. Disabilities of the Arm, Shoulder, and Hand measured using Gabel/Amadio score and disabilities of the arm, shoulder, and hand (DASH) questionnaire at baseline and two years

Overall study start date
01/01/2013

Completion date
11/10/2017

Eligibility

Key inclusion criteria
1. Age >18 years
2. Severe cubital tunnel syndrome (Akahori's Classification grade III, IV, and V)
3. A history of cubital tunnel syndrome >6 months
4. Unilateral limb involvement
5. Atrophy of intrinsic hand muscles innervated by the ulnar nerve, which was defined as a sign of advanced disease, no matter manifestation of grip weakness
6. A conduction velocity of 40 m/s or greater
7. No improvement or worse symptoms in mild disease after 3 months of nonsurgical treatments

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Total final enrolment
90

Key exclusion criteria
1. An additional lesion, such as cervical neuropathy
2. Thoracic outlet syndrome, or Guyon's canal syndrome
3. Deformity or distortion of the cubital tunnel
4. Associated medical conditions capable of causing a non-compressive neuropathy, such as diabetes mellitus and rheumatism
5. Revision surgery for cubital tunnel syndrome

Date of first enrolment

20/01/2013

Date of final enrolment
20/10/2016

Locations

Countries of recruitment
China

Study participating centre
Third Hospital of Hebei Medical University
Ziqiang Road
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Sponsor information

Organisation
Third Hospital of Hebei Medical University

Sponsor details
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Sponsor type
Hospital/treatment centre

Website
http://www.cthhmu.com/

ROR
https://ror.org/004eknx63

Funder(s)

Funder type

Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for this study are unknown and will be available at a later date.

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?
Results article		03/09/2021	17/03/2022	Yes	No