

# Comparing the effectiveness of two treatments for severe cubital tunnel syndrome

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| <b>Submission date</b><br>23/11/2019   | <b>Recruitment status</b><br>No longer recruiting    | <input type="checkbox"/> Prospectively registered    |
| <b>Registration date</b><br>04/07/2020 | <b>Overall study status</b><br>Completed             | <input type="checkbox"/> Protocol                    |
| <b>Last Edited</b><br>17/03/2022       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan   |
|  |  | <input checked="" type="checkbox"/> Results          |
|  |  | <input type="checkbox"/> 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?

Qing Xie

qxie710@sina.com

## Contact information

### Type(s)

Public

### Contact name

Ms Qing Xie

### Contact details

Third Hospital of Hebei Medical University

Shijiazhuang

China

050051

+86-13273148710

qxie710@sina.com

## Additional identifiers

### Protocol serial number

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

## **Study type(s)**

Treatment

## **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(s)**

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

## **Key secondary outcome(s)**

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

## **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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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

Hebei

Shijiazhuang

China

050051

# Sponsor information

## Organisation

Third Hospital of Hebei Medical University

## ROR

<https://ror.org/004eknx63>

# Funder(s)

## Funder type

Other

## Funder Name

Investigator initiated and funded

# Results and Publications

## 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? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a> |         | 03/09/2021   | 17/03/2022 | Yes            | No              |