

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 2026

### Comparative evaluation of the therapeutic results of two methods of ulnar nerve decompression with transposition and ulnar nerve decompression alone in patients with cubital tunnel syndrome

#### Protocol summary

##### Study aim

Comparison of two methods "ulnar nerve decompression with transposition" and "ulnar nerve decompression alone" on improving patients with cubital tunnel syndrome

##### Design

A randomized single-blinding clinical trial, with the parallel groups

##### Settings and conduct

In this study, 50 patients with cubital tunnel syndrome will be included in the study and will be randomly divided into two groups. In one group, decompression surgery will be performed alone and in the other group, decompression and transposition surgery will be performed. Then patients' symptoms improve will be evaluated.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria included the diagnosis of cubital tunnel syndrome by electromyography and nerve conduction velocity (EMG-NCV), non-response to non-surgical treatments performed so far, and Satisfaction to participate in the study. Exclusion criteria are history of hand surgery, history of trauma penetrating the nerves of the hand, and history of cervical neurosurgery.

##### Intervention groups

Intervention group 1: Patients in this group will undergo decompression and transposition surgery. Intervention group 2: Patients in this group undergo only decompression surgery.

##### Main outcome variables

Patient's symptom recovery score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200825048515N17**

Registration date: **2020-12-24, 1399/10/04**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-12-24, 1399/10/04**

Update count: **0**

##### Registration date

2020-12-24, 1399/10/04

##### Registrant information

###### Name

Asieh Maghami Mehr

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 0000 0000

###### Email address

asimaghami@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-12-07, 1399/09/17

##### Expected recruitment end date

2021-01-20, 1399/11/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparative evaluation of the therapeutic results of two methods of ulnar nerve decompression with transposition and ulnar nerve decompression alone in patients with

cubital tunnel syndrome

### Public title

Comparison of two methods "ulnar nerve decompression with transposition" and "ulnar nerve decompression alone" in improving patients with cubital tunnel syndrome

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Diagnosis of cubital syndrome by electromyography and nerve conduction velocity(EMG-NCV) Failure to respond to non-surgical treatments performed so far Satisfaction to participate in the study

#### Exclusion criteria:

History of hand surgery History of trauma penetrating the nerves of the hand History of cervical neurosurgery

### Age

No age limit

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

### Sample size

Target sample size: 50

### Randomization (investigator's opinion)

Not randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

In this study, due to the different use of the two surgical methods, the orthopedic assistant is aware of the type of intervention. But the patient, data collector, and data analyst will not know of the type of patient grouping.

### Placebo

Not used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

### City

Isfahan

### Province

Isfahan

### Postal code

8179964167

### Approval date

2020-12-05, 1399/09/15

### Ethics committee reference number

IR.MUI.MED.REC.1399.800

## Health conditions studied

### 1

#### Description of health condition studied

Cubital Tunnel Syndrome

#### ICD-10 code

G56.20

#### ICD-10 code description

Lesion of ulnar nerve, unspecified upper limb

## Primary outcomes

### 1

#### Description

Symptom improvement score

#### Timepoint

One month, three months, six months and one year after the intervention

#### Method of measurement

Modified Bishop rating system

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group 1: In this group, the patient is located in a supine position, and after closing the tourniquet or Esmarch bandage, and prepping and draping the upper part of the limb. 15 cm skin cutting begins from about 5-6 cm from distal to the posterior medial epicondyle and continues to 10 cm from proximal to the medial epicondyle. After cutting the skin and opening the skin and subcutaneous tissue and protecting the antebrachial cutaneous nerve, the ulnar nerve is explored (posterior to medial intermuscular septum and anterior to the interior head of the triceps). Pressure points on the nerve are released along this path, the arcade of the structure is removed, and the ulnar nerve feeding vessels are retained as long as possible. The ulnar nerve is released and after examination for the absence of pathological lesions and adhesion of the wound, it is washed and repaired skin and under the skin and the dressing and bandage are done by bandaging from the palm crease to the top of the arm.

## Category

Treatment - Surgery

## 2

### Description

Intervention group 2: In this group, the patient is located in a supine position and after closing the tourniquet or Esmarch bandage, and prepping and draping the upper part of the limb. 15 cm skin cutting begins from about 5-6 cm from distal to the posterior medial epicondyle and continues to 10 cm from proximal to the medial epicondyle. After cutting the skin and opening the skin and subcutaneous tissue and protecting the antebrachial cutaneous nerve, the ulnar nerve is explored (posterior to medial intermuscular septum and anterior to the interior head of the triceps). Pressure points on the nerve are released along this path, the arcade of struther is removed, and the ulnar nerve feeding vessels are retained as long as possible. The ulnar nerve is released and after examination for the absence of pathological lesions and adhesion of the wound, it is washed and repaired skin and under the skin and the dressing and bandage is done by bandaging from the palm crease to the top of the arm. The ulnar nerve after the release of the abovementioned path, the entrance to the forearm by keeping the branches of the nerve to the flexor carpi ulnaris muscle and no damage to them is passed to the anterior flexor-pronator mass and under a tab of flexor and pronator group fascia, which is about 1.5 inches long and 1.5 inches wide, is placed and the tab base is in the medial direction and its lateral edge is exposed to the subcutaneous tissue. After transposition and opening of the tourniquet, homeostasis is performed well. The hemovac drain is placed, the skin and under the skin are sewn, and the dressing and bandage are applied with a bandage from the palm crease to the top of the arm.

## Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Al-Zahra Hospital

##### Full name of responsible person

Abolghasem Zarezadeh

##### Street address

Orthopedic Department, Tohid Street, Sefeh Blvd., Al-Zahra Hospital

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

##### Phone

+98 31 3620 2020

##### Email

Rashed\_petro@yahoo.com

## 2

#### Recruitment center

##### Name of recruitment center

Kashani Hospital

##### Full name of responsible person

Abolghasem Zarezadeh

##### Street address

Orthopedic Department, Kashani Hospital, Kashani Street.

##### City

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##### Province

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##### Postal code

8183983434

##### Phone

+98 31 3233 0091

##### Email

Rashed\_petro@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Shaghayegh Haghjoo Javanmard

##### Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

##### Phone

+98 31 3668 8597

##### Email

dean@med.mui.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

No

#### Title of funding source

Isfahan University of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Public

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

#### Type of organization providing the funding

Academic

## Person responsible for general inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Abolghasem Zarezadeh

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

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Orthopedic Department, Al-Zahra Hospital, Sefeh Blvd., Tohid Street

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Rashid Rahmati

**Position**

Resident

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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**Email**

Rashed\_petro@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Abolghasem Zarezadeh

**Position**

Associate Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Orthopedics

**Street address**

Orthopedic Department, Al-Zahra Hospital, Sefeh Blvd., Tohid Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174675731

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

There is no further information

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available