Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Nov 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 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
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Iran (Islamic Republic of)
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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
Isfehan
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
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Orthopedic Department, Tohid Street, Sefeh Blvd., Al-Zahra Hospital
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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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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