

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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

Isfahan

Province

Isfahan

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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

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

Phone

+98 31 3620 2020

Email

Rashed_petro@yahoo.com

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

Street address

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

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

Rashed_petro@yahoo.com

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