

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of long term effectiveness of open surgery versus ultrasound guided median nerve hydrodissection in terms of symptoms , function and electrophysiological studies in patients with Canal Tunnel syndrome(CTS)

Protocol summary

Study aim

Comparison of long term effectiveness of open surgery versus ultrasound guided median nerve hydrodissection in terms of symptoms , function and electrophysiological studies in patients with CTS

Design

There are two groups of clinical trials 40 patients in the age range of 20 to 65 years with moderate to severe CTS were randomly divided into two groups of 20 people random allocation is done in random blocks with block size 4 and block number 10. Thus, based on AABB letter permutations, we produce a list of 40 letters A and B and assign them to patients, respectively.

Settings and conduct

this study, were to Shahid Beheshti Hospital in Babol The first group undergoes open surgery cut 2.5 cm in length at a distance of 1.5 cm We create a distal meter to the wrist in the direction of the fourth finger., we release the distal end of the transverse ligament to the proximal to show the median nerve

Participants/Inclusion and exclusion criteria

In this study, 40 patients with carpal tunnel syndrome who referred to Shahid Beheshti Hospital in Babol during 1397-1397 and will undergo open surgery and release of the median nerve with ultrasound vision with liquid and local steroid injection, are included in the study Patients with systemic disease, such as inflammatory joint disease, diabetes, hypothyroidism, with a history of CTS surgery or nerve damage

Intervention groups

A group undergoes open surgery . The other group undergoes median nerve release by ultrasound with fluid and topical steroid injections.

Main outcome variables

The rate of improvement in patients' symptoms The rate of improvement in patients' function after open surgery

The rate of improvement of patients' electrophysiological parameters

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141121020020N8**

Registration date: **2021-09-21, 1400/06/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-09-21, 1400/06/30**

Update count: **0**

Registration date

2021-09-21, 1400/06/30

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-23, 1400/06/01

Expected recruitment end date

2022-03-16, 1400/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of long term effectiveness of open surgery versus ultrasound guided median nerve hydrodissection in terms of symptoms , function and electrophysiological studies in patients with Canal Tunnel syndrome(CTS)

Public title

Comparison of long term effectiveness of open surgery versus ultrasound guided median nerve hydrodissection in terms of symptoms , function and electrophysiological studies in patients with Canal Tunnel syndrome(CTS)

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

all patients with carpal tunnel syndrome referred to Shahid Beheshti Hospital in Babol during 1397-98

Exclusion criteria:**Age**

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random allocation is done in random blocks with block size 4 and block number 10. Thus, based on AABB letter permutations, we produce a list of 40 letters A and B and assign them to patients, respectively.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

IR.MUBABOL.HRI.REC

Street address

Keshavarz street rohani hospital

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BABOL

Province

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Postal code

4717641367

Approval date

2021-08-22, 1400/05/31

Ethics committee reference number

IR.MUBABOL.HRI.REC.1400.045

Health conditions studied**1****Description of health condition studied**

Carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes**1****Description**

The rate of improvement in patients' symptoms

Timepoint

a special questionnaire for the evaluation of CTS patients, which is filled out once before surgery and three times at 1, 3 and 6 months after surgery

Method of measurement

This questionnaire was designed by David W et al., Which is the Boston questionnaire, which consists of two tables, one to assess symptoms and the other to assess patient performance. In total, the patient gets a score between 11-55 for symptoms and 8-40 for function

Secondary outcomes**1****Description**

The rate of improvement of patients' electrophysiological parameters after open surgery and release of the median nerve

Timepoint

To evaluate patients, the electrophysiological study of patients (EMG-NCV) and a special questionnaire for the evaluation of CTS patients, which is filled out once before surgery and three times at 1, 3 and 6 months after surgery, are used to evaluate the outcome of the operation

Method of measurement

This questionnaire was designed by David W et al., Which is the Boston questionnaire, which consists of two tables, one to assess symptoms and the other to assess patient performance. In total, the patient gets a score

between 11-55 for symptoms and 8-40 for function. The higher this number, the more severe the person's disease

Intervention groups

1

Description

We create a distal meter to the wrist in the direction of the fourth finger. After removing the adipose tissue and aponeurosis, we release the distal end of the transverse ligament. Then, this ligament formsIt is cut lengthwise from the distal to the proximal to show the median nerve

Category

Treatment - Surgery

2

Description

Intervention group: The second group, with the help of median nerve ultrasound from forearm to wrist under CFT ligament(Common Flexor Tendon) is specified. With the help of a special block needle that can be detected by sonography (Sonovisible needle), it is guided directly from the ulnar wrist under the CFT and by slow injection of the fluid combination with local anesthesia of bupivacaine and depomedrol, the median nerve is separated from the CFT

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

بیمارستان شهید بهشتی و بیمارستان آیت اله روحانی

Full name of responsible person

Merafza Mir

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Recruitment center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol University of Medical Sciences

Proportion provided by this source

50

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

Babol University of Medical Sciences

Full name of responsible person

Mehrafza Mir

Position

Assistant Professor of Anesthesiology

Latest degree

Specialist

Other areas of specialty/work

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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 are no plans to publish it yet.

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available