

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Comparison of the effectiveness of open surgery versus ultrasound guided median nerve dissection with injection of methyl prednisolone acetate in treatment of carpal tunnel syndrome

Protocol summary

Study aim

Determine the comparison of the effectiveness of open surgery versus ultrasound guided median nerve dissection with injection of methyl prednisolone acetate in treatment of carpal tunnel syndrome

Design

In this study, 40 patients have been assigned to two groups of intervention and control by using random numbers table.

Settings and conduct

In this clinical trial, all patients who undergo surgery in Shahid Beheshti Hospital with carpal tunnel syndrome diagnosis include the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria includes Patients age 20-65 years old with patients with carpal tunnel syndrome Informed consent of patient in the study. Exclusion criteria include neuropathy or an old nerve injury; Patients with systemic disease, such as disease, arthritis, diabetes, hypothyroidism ; dissatisfaction to fill consent paper.

Intervention groups

One group was treated with open surgery and the other group was treated by injection of Depo- MdroI under sonographic guidance.

Main outcome variables

Pain, Paresthesia, Numbness, Weakness, Return to daily activities, sonographic improvement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200629047948N1**

Registration date: **2020-06-29, 1399/04/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-06-29, 1399/04/09**

Update count: **0**

Registration date

2020-06-29, 1399/04/09

Registrant information

Name

Amir Hossein Zohrehvand

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-03-18, 1398/12/28

Expected recruitment end date

2021-03-14, 1399/12/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of open surgery versus ultrasound guided median nerve dissection with injection of methyl prednisolone acetate in treatment of carpal tunnel syndrome

Public title

Comparison of the effectiveness of open surgery versus ultrasound guided median nerve dissection with injection

of methyl prednisolone acetate in treatment of carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 20-65 years patients with carpal tunnel syndrome
Informed consent of patient in the study.
Exclusion criteria:
Neuropathy or an old nerve injury Patients with systemic disease, such as disease, arthritis, diabetes, hypothyroidism Dissatisfaction to fill consent paper

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

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
Samples will be divided into two groups of Control and intervention using Permuted Block Randomization. Number will be selected for allocation concealment by one of the colleagues and by another, that assignment chain is chosen.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Babol University of Medical Sciences
Street address
Babol University of Medical Sciences, Ganjafrooz Street, Babol, Mazandaran, Iran
City
Babol
Province
Mazandaran
Postal code
4716681451
Approval date
2020-03-14, 1398/12/24

Ethics committee reference number
IR.MUBABOL.HRI.REC.1398.372

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

Pain

Timepoint

Before surgery and one and three month of surgery

Method of measurement

Visual Analogue Scale

2

Description

Paresthesia

Timepoint

Before surgery and one and three month of surgery

Method of measurement

Based on patient response

3

Description

Numbness

Timepoint

Before surgery and one and three month of surgery

Method of measurement

Based on boston form

4

Description

weakness

Timepoint

Before surgery and one and three month of surgery

Method of measurement

Based on boston form

Secondary outcomes

1

Description

Return to daily activities

Timepoint

Before surgery and one and three month of surgery

Method of measurement

Based on boston form

2

Description

Sonographic improvement

Timepoint

Before surgery and one and three month of surgery

Method of measurement

Median nerve cross sectional area on ultrasound

Intervention groups

1

Description

Intervention group: Undergoes open surgery using the Fallen method.

Category

Treatment - Surgery

2

Description

Control group: patient lies prone an wrist sets in supine position. median nerve is visualized by sonographic guidance at wrist area. after local analgesia a 22 gauge needle will be entered from ulnar side of median nerve and carpal ligament starts to be fenestrated. at the end 20 miligram of Bupivacaine with 40 miligram Depomedrol and 3-5 cc normal saline is injected and needle is removed.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Shahid Beheshti Hospital

Full name of responsible person

Dr. Amir Hossien Zohrehvand

Street address

Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Dr. Reza Ghadimi

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Babol University of Medical Sciences; Ganjafrooz Street; Babol; Iran

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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

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

Babol University of Medical Sciences

Full name of responsible person

Parmida abdavy

Position

General Medicine

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Babol University of Medical Sciences

Full name of responsible person

Dr. Amir hossein Zohrehvand

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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Person responsible for updating data

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Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Neurosurgery

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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**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