Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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- Mdrol 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

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Amir Hossein Zohrehvand

Name of organization / entity

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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
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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
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
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Parmida abdavy
Position
General Medicine
Latest degree
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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