

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Double Incision and Comparison of the outcomes of Minimal Incision technique in treatment of carpal tunnel syndrome

Protocol summary

Study aim

Choosing the right surgery method for carpal tunnel syndrome

Design

In this study, 50 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 diagnosed with carpal tunnel syndrome. Exclusion criteria include failure to follow the patient after surgery, recurrence of carpal tunnel syndrome after CTR surgery, patients whose symptoms are severe, such as trauma, fracture, bleeding, and injury during surgery.

Intervention groups

One group was treated with double incision and another group with minimal incision.

Main outcome variables

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

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160508027797N5**

Registration date: **2019-03-11, 1397/12/20**

Registration timing: **registered_while_recruiting**

Last update: **2019-03-11, 1397/12/20**

Update count: **0**

Registration date

2019-03-11, 1397/12/20

Registrant information

Name

Masoud Bahrami Ferydoni

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3225 6285

Email address

m.bahrami@mubabol.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-18, 1397/08/27

Expected recruitment end date

2019-11-18, 1398/08/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Double Incision and Comparison of the outcomes of Minimal Incision technique in treatment of carpal tunnel syndrome

Public title

Double Incision and Comparison of the outcomes of Minimal Incision technique in treatment of carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with carpal tunnel syndrome

Exclusion criteria:

Failure to follow the patient after surgery Carpal tunnel syndrome recurs after CTR surgery Patients whose symptoms are severe, such as trauma, fracture, bleeding, and damage during surgery.

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description

These patients are divided into 2 groups of 25 Minimal Incision and Double Incision according to the random numbers table.

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

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

2018-11-18, 1397/08/27

Ethics committee reference number

IR.MUBABOL.HRI.REC.1397.207

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 six month of surgery

Method of measurement

Visual Analogue Scale

2

Description

Paresthesia

Timepoint

Before surgery and six month of surgery

Method of measurement

Based on patient response

3

Description

Numbness

Timepoint

Before surgery and six month of surgery

Method of measurement

Based on boston form

4

Description

weakness

Timepoint

Before surgery and six month of surgery

Method of measurement

Based on boston form

Secondary outcomes

1

Description

Return to daily activities

Timepoint

Before surgery and six month of surgery

Method of measurement

Based on boston form

Intervention groups

1

Description

Intervention group: Minimal Incision Surgery

Category

Treatment - Surgery

2

Description

Control group: Double Incision Surgery

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Babol Shahid Beheshti Hospital

Full name of responsible person

Dr. Masoud Bahrami Ferydoni

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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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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

Dr. Ilia Roshani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Masoud Bahrami Ferydoni

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

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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