

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of two open surgical procedures with release and without release of antebrachial fascia in patients with bilateral carpal tunnel syndrome

Protocol summary

Study aim

Comparison of two open surgical procedures with release and without release of antebrachial fascia in patients with bilateral carpal tunnel syndrome

Design

Double blind randomized clinical trials

Settings and conduct

This study is a randomized, double-blind clinical trial. Patient would enter to study according to inclusion and exclusion criteria. In this study, simple randomization method will be used. The participants will be classified into two groups by computer and the type of operation was placed in a sealed envelope and the surgeon performed the procedure according to it, but the surgeon Did not know about the type of operation before peration. Patients before surgery and outcome evaluationer will not know about type of surgery. This study will established in Imam Khomeini Hospital of Sari and intervention will be release of carpal tunnel with or without anti-brachial fascia release in case and control group, respectively. patients will be followed 1 week, 1 month, 3 months and 6 months after surgery. The primary outcome will be assessed using the Boston carpal tunnel questionnaire. Other outcomes included patient satisfaction based on standard visual analog scale, short Questionnaire Disability of shoulder, elbow and hand (quick dash), and pinch and grip strength.

Participants/Inclusion and exclusion criteria

The major inclusion criteria were: sensory loss or numbness in the median nerve distribution, positive Tinel sign, positive Phalen's test, moderate or severe CTS on electrophysiological testing, no response, or relapse following conservative treatment for a minimum 3 months; The major exclusion criteria were: history of carpal tunnel surgery, inflammatory arthropathy or peripheral neuropathy, spine, shoulder, or elbow pathology, history of hand trauma, onset of CTS during

pregnancy, previous CTR in the contralateral hand, recurrent CTS, age less than 18 years

Intervention groups

Intervention group One: A group that has open surgery with releasing the antebrachia fascia. Intervention group Two: A group that has open surgery without releasing the antebrachia fascia.

Main outcome variables

Reduced Boston Carpal tunnel questionnaire score; Reduction of visual analog scale; Reduced scores for short Questionnaire Disability of shoulder, elbow and hand; Increased pinch and grip strength

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120726010405N4**
Registration date: **2018-02-26, 1396/12/07**
Registration timing: **retrospective**

Last update: **2018-02-26, 1396/12/07**

Update count: **0**

Registration date

2018-02-26, 1396/12/07

Registrant information

Name

mehran razavipour

Name of organization / entity

mazandaran university of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1325 7230

Email address

m.razavipour@mazums.ac.ir

Recruitment status**Recruitment complete****Funding source**

Vice chancellor for reseearch, Mazandaran University of Medical Science

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2018-01-20, 1396/10/30

Actual recruitment start date

2016-09-22, 1395/07/01

Actual recruitment end date

2018-01-20, 1396/10/30

Trial completion date

empty

Scientific title

Comparison of two open surgical procedures with release and without release of antebrachial fascia in patients with bilateral carpal tunnel syndrome

Public title

Comparison of two open surgical procedures with release and without release of antebrachial fascia in patients with bilateral carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

sensory loss or numbness in the median nerve distribution positive Tinel sign positive Phalen's test moderate or severe CTS on electrophysiological testing no response, or relapse following conservative treatment for a minimum 3 months

Exclusion criteria:

history of carpal tunnel surgery inflammatory arthropathy or peripheral neuropathy spine, shoulder, or elbow pathology history of hand trauma onset of CTS during pregnancy recurrent CTS age less than 18 years

AgeFrom **18 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample sizeTarget sample size: **38**Actual sample size reached: **38****Randomization (investigator's opinion)**

Randomized

Randomization description

In this study, simple randomization method was used. The participants were classified into two groups by computer and the type of operation was placed in a sealed envelope and and the surgeon performed the procedure according to it, but the surgeon Did not know about the type of operation before it.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study,Patients before surgery and outcome evaluationer did not know about type of surgery.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Mazandaran University of Medical Science

Street address

Deputy of Research and Technology of Mazandaran University of Medical Sciences,Moalem Sq., Moalem St., Sari

City

Sari

Province

Mazandaran

Postal code

۳۳۹۷۱-۴۸۱۵۷

Approval date

2016-10-17, 1395/07/26

Ethics committee reference number

IR.MAZUMS.IMAMHOSPITAL.REC.95.2545

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**

Boston carpal tunnel (BCT) score

Timepoint

Before surgery,1,3,6 after surgery

Method of measurement

The severity scale-Functional status scale-Boston carpal tunnel (BCT)

Secondary outcomes

1

Description

patient's satisfaction

Timepoint

After surgery

Method of measurement

scale visual analog scale

Intervention groups

1

Description

Intervention group: The release of the carpal tunnel with the release of the anti-brachial fascia, in which a 2 cm incision in the proximal palmar on the transverse ligament of the wrist will be performed, starting with the Kaplan's cardinal line. After the incision of skin, the subcutaneous tissue is cut with a Surgical Blade number 15 and the two edges of the cut are fixed with the retractor. The palmar fascia will be opened and the wrist ligation will be detected. The transverse ligament will be accessed with a Surgical Blade No. 15 in order to provide access to the carpal tunnel and the median nerve is also detected. The transverse ligament will be opened to the distal part by scissors, and the anti-brachial fascia will be released as blunt to the proximal. Incision site will be folded by 0.4 Nylon thread and pressure bandage will be applied to it.

Category

Treatment - Surgery

2

Description

Control group: The release of the carpal tunnel without the release of the anti-brachial fascia, in which a 2 cm incision in the proximal palmar on the transverse ligament of the wrist will be performed, starting with the Kaplan's cardinal line. After the incision of skin, the subcutaneous tissue is cut with a Surgical Blade number 15 and the two edges of the cut are fixed with the retractor. The palmar fascia will be opened and the wrist ligation will be detected. The transverse ligament will be accessed with a Surgical Blade No. 15 in order to provide access to the carpal tunnel and the median nerve is also detected. The transverse ligament will be opened to the distal part by scissors. Incision site will be folded by 0.4 Nylon thread and pressure bandage will be applied to it.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Doctor Mehran Razavi Pour

Street address

Imam Khomeini Hospital, Amir Mazandarani St., Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3337 7169

Email

m.razavipour@mazums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mazandaran University of Medical Science

Full name of responsible person

Doctor Ahmad Ali Enayati

Street address

Deputy of Research and Technology of Mazandaran University of Medical Science, Moalem Sq., Moalem St., Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3337 7169

Email

m.razavipour@mazums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mazandaran University of Medical Science

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

Mazandaran University of Medical Sciences

Full name of responsible person

Dr seyed Mehran Razavipour

Position

Hand Surgery

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Mazandaran University of Medical Sciences, First of
Vali Asr HWY., Joibar Junction, Emam Sq., Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+1 133377169

Fax**Email**

m.razavipour@mazums.ac.ir

Web page address**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Doctor Sadegh Taheri

Position

Orthopedic resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

Street address

Mazandaran University of Medical Sciences, First of
Vali Asr HWY., Joibar Junction, Emam Sq., Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3337 7169

Fax**Email**

m.razavipour@mazums.ac.ir

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Dr seyed Mehran Razavipour

Position

Hand Surgery

Latest degree

Subspecialist

Other areas of specialty/work

Orthopedics

Street address

Mazandaran University of Medical Sciences, First of
Vali Asr HWY., Joibar Junction, Emam Sq., Sari

City

Sari

Province

Mazandaran

Postal code

4815733971

Phone

+98 11 3337 7169

Fax**Email**

m.razavipour@mazums.ac.ir

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

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

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