Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 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

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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
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target 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 facia will be opened and the wrist ligation will detected. The transverse ligament will 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 facia will be opened and the wrist ligation will detected. The transverse ligament will 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
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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
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Deputy of Research and Technology of Mazandaran University of Medical Science, moalem Sq., Moalem St., Sari
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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
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
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Person responsible for scientific inquiries

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Position
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Latest degree
Subspecialist
Other areas of specialty/work
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Person responsible for updating data

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Doctor Sadegh Taheri
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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