Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparing the surgical outcomes of carpal tunnel syndrome treatment between open carpal tunnel release (OCTR) and thread carpal tunnel release (TCTR)

Protocol summary

Study aim
Comparing the surgical outcomes of carpal tunnel syndrome treatment between open carpal tunnel release (OCTR) and thread carpal tunnel release (TCTR)

Design
Randomized phase 3 clinical trial on 20 patients, with simple randomization

Settings and conduct
This randomized clinical trial will conduct at Hazrat-e-Fatemeh hospital in 2022. The randomization will conduct by simple randomization in a 1:1 allocation and patients will receive OCTR or TCTR as treatment.

Participants/Inclusion and exclusion criteria
Mild cases (sensory nerve action potential more than 3.6 m.s in the electrodiagnostic study) and moderate cases (sensory nerve action potential more than 3.6 m.s, and compound muscle action potential more than 4.2 m.s in the electrodiagnostic study) of CTS whit positive Phalen test and lack of response to non-surgical treatments will be included. Thenar atrophy, severe CTS (lack of sensory nerve action potential and compound muscle action potential and nerve conduction velocity less than 40 m/s across the wrist), neurodegenerative/ demyelinating diseases, history of surgical treatment or corticosteroid injection for carpal tunnel syndrome in last 6 months, and lack of consent for inclusion into the study are the exclusion criteria.

Intervention groups
In the open surgery group, the proximal wrist groove will open and after exposing the median nerve, the guiding groove will pass from inside to the fourth finger and then the ligament will be released using scissors. In the thread surgery group, after determining the safe zone points and opening the palmar fascia, and inserting the endoscope from the proximal to the distal part of the safe zone, a nylon thread No. 1 will pass from the distal to the proximal region below the transverse carpal ligament (TCL) and the TCL will release by abrasion and friction moves.

Main outcome variables
Aesthetic outcomes, nerve-muscle study, operation time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211225053519N2**
Registration date: **2022-01-10, 1400/10/20**
Registration timing: **prospective**

Last update: **2022-01-10, 1400/10/20**
Update count: **0**

Registration date
2022-01-10, 1400/10/20

Registrant information

Name
Mohammad Amin Shahrbaf
Name of organization / entity
Royan Institute
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-01-21, 1400/11/01

Expected recruitment end date
2022-03-11, 1400/12/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparing the surgical outcomes of carpal tunnel syndrome treatment between open carpal tunnel release (OCTR) and thread carpal tunnel release (TCTR)

Public title
Comparing open and closed thread surgical techniques in carpal tunnel syndrome
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Clinical symptoms of carpal tunnel syndrome Positive Phalen Test Mild cases of carpal tunnel syndrome (sensory nerve action potential (SNAP) more than 3.6 m.s in the electrodiagnostic study) Moderate cases of carpal tunnel syndrome (sensory nerve action potential (SNAP) more than 3.6 m.s and compound muscle action potential (CMAP) more than 4.2 m.s in the electrodiagnostic study) Lack of responses to non-surgical treatments
Exclusion criteria:
Thenar atrophy Severe cases of carpal tunnel syndrome (lack of sensory nerve action potential (SNAP) and compound muscle action potential (CMAP) and nerve conduction velocity (NCV) less than 40 m/s across the wrist) Neurodegenerative or demyelinating diseases History of surgical treatment for carpal tunnel syndrome in last 6 months History of corticosteroid injection for carpal tunnel syndrome in last 6 months Lack of consent for inclusion into the study
Age
No age limit
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **20**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, we will use the simple randomization method. Random allocation software is also used as the randomization tool. The allocation concealment will be used for hiding so that the assigned group is not known before the individual is assigned. Using opaque envelopes sealed with random sequences, each of the random sequences created is recorded on a card, and the cards are placed in the envelopes, respectively. To maintain a random series, the envelopes are numbered in the same way on the outer surface. Finally, the lids of the envelopes are glued and placed in a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants into the study, one of the envelopes of the letter is opened in order, and the assigned group of the participant is revealed.
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
Research Ethics Committees of School of Medicine, Iran University of Medical Sciences
Street address
Tehran Hemat Highway next to Milad Tower
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2019-08-07, 1398/05/16
Ethics committee reference number
IR.IUMS.FMD.REC.1398.194

Health conditions studied

1

Description of health condition studied
Carpal Tunnel Syndrome
ICD-10 code
G56
ICD-10 code description
Mononeuropathies of upper limb

Primary outcomes

1

Description
Scar length in centimeter
Timepoint
3 month after the surgery
Method of measurement
Direct observation

2

Description
Postsurgical pain
Timepoint
One day after the surgery
Method of measurement
Visual analog score (VAS)

3

Description
Operation time in minute
Timepoint
During the operation
Method of measurement
Assessing the minutes by clock

4

Description
Two point discriminations in thumb and index fingers
Timepoint
One month after the surgery
Method of measurement
Sensing two point discriminations based on millimeters

5

Description
Monofilament test
Timepoint
One month after the operation
Method of measurement
Monofilament assessment

6

Description
Electrodiagnostic assessment
Timepoint
One month after the operation
Method of measurement
Electrodiagnostic study

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the open surgery group, after a 1 cm incision, the proximal wrist groove will open and after exposing the median nerve, the guiding groove will pass from inside to the fourth finger and then the ligament will be released using scissors.
Category
Treatment - Surgery

2

Description
Intervention group: In the thread surgery group, after determining the safe zone points and opening the palmar fascia, and inserting the endoscope from the proximal to the distal part of the safe zone, a nylon thread No. 1 will pass from the distal to the proximal region below the transverse carpal ligament (TCL) and the TCL will release by abrasion and friction moves.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat-e Fatemeh Hospital
Full name of responsible person
Mohammad Reza Akhoondi nasab
Street address
21th Alley, Seyed Jamaloddin Asad Abadi St., Tehran, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Reza Akhoondi nasab
Street address
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Aminshahrbaf41@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source
Iran 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
Iran University of Medical Sciences

Full name of responsible person
Mohammad Amin Shahrbaf

Position
Research Assistant

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
All Deidentified Individual Participant Data Set will be available after the end of the study

When the data will become available and for how long
6 months after publishing the results

To whom data/document is available
Researchers who work in an academic institute

Under which criteria data/document could be used
Data is given to the researchers just for assessment and not for interfering

From where data/document is obtainable

Through email: Me_service22@yahoo.com

What processes are involved for a request to access data/document

The data will given to researchers after assessing the eligibility through email

Comments