

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 with 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 Shahrbafe

Name of organization / entity

Royan Institute

Country

Iran (Islamic Republic of)

Phone

+98 21 4496 0244

Email address

aminshahrbafe41@gmail.com

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

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Email

crtfatima@iums.ac.ir

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

21th Alley, Seyed Jamaloddin Asad Abadi St., Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1433933111

Phone

+98 21 8871 7272

Email

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 Shahrbafe
Position
Research Assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
21th Alley, Seyed Jamaloddin Asad Abadi St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14665354
Phone
+98 21 8871 7272
Email
Aminshahrbafe41@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Amin Shahrbafe
Position
Research Assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
21th Alley, Seyed Jamaloddin Asad Abadi St., Tehran, Iran
City
Tehran
Province

Tehran
Postal code
14665354
Phone
+98 21 8871 7272
Email
Aminshahrbafe41@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Mohammad Amin Shahrbafe
Position
Research Assistant
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
21th Alley, Seyed Jamaloddin Asad Abadi St., Tehran, Iran
City
Tehran
Province
Tehran
Postal code
14665354
Phone
+98 21 8871 7272
Email
Aminshahrbafe41@gmail.com

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