

# 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**

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##### **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

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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 Shahrbafe  
**Position**  
Research Assistant  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
General Surgery  
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21th Alley, Seyed Jamaloddin Asad Abadi St., Tehran,  
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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
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**Full name of responsible person**  
Mohammad Amin Shahrbafe  
**Position**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Iran University of Medical Sciences  
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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**