

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Comparison between the effect of two minimally invasive standard surgical method (without removing apart of the transverse carpal ligament) and the surgical method along removing a part of the transverse carpal ligament longitudinally on the release of the median nerve in preventing the recurrence of carpal tunnel syndrome in orthopedic surgery.

Protocol summary

Study aim

Comparison between the effect of standard minimally invasive surgery and the surgical method along removing a part of the transverse carpal ligament longitudinally, on the release of the median nerve in the prevention of CTS recurrence.

Design

The clinical trial includes a control group and parallel, single-blind, randomized clinical groups with a sample size determined according to Cohen's formula for clinical trials and using G-power software, 52 patients. Randomization is done using block randomization method.

Settings and conduct

Patients with Moderate and severe carpal tunnel syndrome referring to the orthopedic clinic of Madani Hospital will be included in this study and they will be divided into intervention and control groups with the help of rand excel function. Patients in the intervention group will undergo standard carpal tunnel surgery along with the removal of a part of the transverse ligament. In contrast, patients in the control group will undergo a standard minimally invasive surgery. All interventions will be performed by one orthopedic surgeon. All patients will be discharged one day after surgery and will be visited periodically for 12 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with moderate to severe median nerve entrapment who have undergone physical and clinical evaluations and/or EMG diagnosis. Exclusion criteria: Patients who have previously undergone surgical treatment or have had bone fractures, blunt trauma, or sharp wrist injuries.

Intervention groups

The intervention group includes patients with carpal tunnel syndrome who will undergo standard surgery along with removing part of the transverse carpal ligament longitudinally. group. Control includes patients with carpal tunnel syndrome who will undergo standard minimally invasive surgery

Main outcome variables

Recurrence rate of carpal tunnel syndrome a year after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230317057746N1**
Registration date: **2023-06-20, 1402/03/30**
Registration timing: **prospective**

Last update: **2023-06-20, 1402/03/30**

Update count: **0**

Registration date

2023-06-20, 1402/03/30

Registrant information

Name

Hamed Jokar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 7760 8607

Email address

h.jokar@abzums.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-07-23, 1402/05/01

Expected recruitment end date
2023-10-23, 1402/08/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison between the effect of two minimally invasive standard surgical method (without removing apart of the transverse carpal ligament) and the surgical method along removing a part of the transverse carpal ligament longitudinally on the release of the median nerve in preventing the recurrence of carpal tunnel syndrome in orthopedic surgery.

Public title
The effect of various surgical methods in preventing the recurrence of carpal tunnel syndrome.

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
Patient who comes to orthopedic clinic with carpal tunnel syndrome. Patient who diagnosis mild to moderate compression of the median nerve.

Exclusion criteria:
Patient who has wrist surgical history. Patient who has wrist bone fracture, blunt and sharp trauma.

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: 52

Randomization (investigator's opinion)
Randomized

Randomization description
The block randomization method will be used for randomization. The length of the block for each of the treatment groups is considered to be 4, that is, each block includes two people from the intervention group and two people will be from the comparison group. Then for each of these blocks Random codes will be generated. Then one of these blocks will be randomly selected and based on the sequence of letters A and B in

the selected block, eligible people will be assigned to treatment or comparison groups. This random process of selecting blocks and assigning people to The intervention and comparison groups will continue until the desired sample size is reached.

Blinding (investigator's opinion)
Double blinded

Blinding description
The present study will be conducted in a two-way blind. After giving complete explanations about both surgical methods and reassuring the patients, the patients will be hospitalized and undergo the procedure without knowing the type of surgery. Then, independent researchers will collect information specific to patient outcomes without knowing the group to which the patients are referred.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Madani hospital, Mahan Ave, Shahid Taleghani Ave, Karaj, Iran.

City

Karaj

Province

Alborz

Postal code

3143744693

Approval date

2023-02-22, 1401/12/03

Ethics committee reference number

IR.ABZUMS.REC.1401.318

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

the recurrence of carpal tunnel syndrome.

Timepoint

Examining the recurrence symptoms of carpal tunnel syndrome at the beginning of the study, the third, sixth, ninth and twelfth months after surgery.

Method of measurement

Telephone interviews using a standardized and detailed checklist along with periodic examinations.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Surgical method along with removing a part of the transverse carpal ligament longitudinally

Category

Treatment - Surgery

2

Description

Control group: Standard minimally invasive surgery (without removing part of the transverse ligament)

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Orthopedic Clinic of Karaj Madani Hospital

Full name of responsible person

Dr. Mohammad Sajjad Mirhoseini

Street address

Madani hospital, Mahan Ave, Shahid Taleghani Ave, Karaj, Iran.

City

Karaj

Province

Alborz

Postal code

3143744693

Phone

+98 26 3442 7001

Email

madani@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Mohammad Sajjad Mirhoseini

Street address

Deputy of research and technology , Safareyan St, Golshahr Ave, Karaj

City

Karaj

Province

Alborz

Postal code

3198764653

Phone

+98 26 3464 3922

Email

Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Sajjad Mirhoseini

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Madani hospital, Mahan Ave, Shahid Taleghani Ave, Karaj, Iran.

City

Karaj

Province

Alborz

Postal code

3143744693

Phone

+98 26 3442 7001

Email

smirortho@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr. Mohammad Sajjad Mirhoseini

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Orthopedics

Street address

Madani hospital, Mahan Ave, Shahid Taleghani Ave,
Karaj, Iran.

City

Karaj

Province

Alborz

Postal code

3143744693

Phone

+98 26 3442 7001

Email

smirortho@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Hamed Jokar

Position

Student(intern)

Latest degree

A Level or less

Other areas of specialty/work

Orthopedics

Street address

No.6, 17th St., Moshki St., Ibn Sina Sq

City

Tehran

Province

Tehran

Postal code

1154714313

Phone

+98 21 7760 8607

Fax**Email**

h.jokar@abzums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

This is because there is a possibility of disclosure of patients' information due to the lack of number of studied cases.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available