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)

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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.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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
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Person responsible for updating data

Contact

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Position
Student(intern)

Latest degree
A Level or less

Other areas of specialty/work
Orthopedics

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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