

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jul 2026

Comparing two surgical methods (classical incision method and 1-2 mm margin removal method by ulnar tunnel) in treating carpal tunnel syndrome

Protocol summary

Study aim

Comparing two surgical methods in treating carpal tunnel syndrome: classical incision method and 1-2 mm margin removal method by ulnar tunnel

Design

Randomized controlled trial, parallel groups, sample size:70, double blind, randomized:block allocation

Settings and conduct

70 patients with carpal tunnel syndrome in the wrist comprised the study population and did not respond to supportive treatment and were hospitalized in Ayatollah Taleghani Hospital. Patients were classified into two groups of surgery (35 people per each group) by classical incision method and 1-2 mm margin removal from the ulnar tunnel for carpal tunnel syndrome surgery. Boston questioner complete outpatient before and 6 month after surgery, participants and parson who collected questioners don't know about the type of surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who were diagnosed with the disease based on clinical and electrodiagnostic symptoms, did not respond to non-surgical treatments, at least 6 months have passed since their illness or at least one of the criteria: disease period more than 10 months, age older than 50 years, Phalen-positive test for less than 30 seconds, permanent anesthesia, Tenosynovitis at the first visit. Exclusion criteria: Thenar atrophy, history of early carpal tunnel surgery, history of wrist fracture, pregnancy, history of tendon injury and wrist surgery, presence of a lesion on the wrist.

Intervention groups

Patients were classified into two groups of surgery by classical incision method and 1-2 mm margin removal from the ulnar tunnel for carpal tunnel syndrome surgery

Main outcome variables

Boston questioner (evaluate pain and function)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200307046711N2**

Registration date: **2021-06-25, 1400/04/04**

Registration timing: **prospective**

Last update: **2021-06-25, 1400/04/04**

Update count: **0**

Registration date

2021-06-25, 1400/04/04

Registrant information

Name

Narges Nikpay

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3231 9040

Email address

n_nikpay@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-05, 1400/04/14

Expected recruitment end date

2022-02-03, 1400/11/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing two surgical methods (classical incision method and 1-2 mm margin removal method by ulnar tunnel) in treating carpal tunnel syndrome

Public title

Comparing two types of surgical methods in treating carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diagnosed carpal tunnel syndrome based on clinical and electrodiagnostic symptoms No respond to non-surgical treatments at least after 6 months or at least one of the criteria: disease period more than 10 months, age older than 50 years, Phalen-positive test for less than 30 seconds, permanent anesthesia, Tenosynovitis at the first visit

Exclusion criteria:

Thenar atrophy History of early carpal tunnel surgery History of wrist fracture, pregnancy History of tendon injury and wrist surgery Presence of a lesion on the wrist

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Participants allocate in to two groups by block randomized method, blocks in size of four are considered, first group is shown with A character and the second with B. by use of random allocation software sequence of different permutations of quadric blocks are made that define allocation of participants in groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and person who accumulate Boston questioner, don't know the type of surgery because operation is done by another person in hospital. Boston questioners are completed outpatient by orient person before and 6 month after surgery.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah university of medical science

Street address

Shahid beheshti Blvd, Kermanshah town

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2020-08-21, 1399/05/31

Ethics committee reference number

IR.KUMS.REC.1399.468

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

Boston questioner(pain and function)

Timepoint

Before and 6 months after intervention

Method of measurement

Boston questioner

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intervention group: carpal tunnel syndrome surgery by resection of 1-2 millimeters from ulnar side

Category

Treatment - Surgery

2

Description

Control group: Control group: carpal tunnel syndrome

surgery by classic incision
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Taleqani hospital
Full name of responsible person
Ali mousapoor
Street address
Beheshti Blvd, Kermanshah town
City
Kermanshah
Province
Kermanshah
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6715847141
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ali.mousapour@kums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Farid Najafi
Street address
Shahid Beheshti Blvd, kermanshah
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Email
farid_n32@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
Saeid Nikbakht
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for updating data

Contact

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Full name of responsible person

Saeid Nikbakht

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

Collected data is shareable after people were deidentified.

When the data will become available and for how long

Starting 6 months after publication.

To whom data/document is available

The data is available only for people who work in academic institutions.

Under which criteria data/document could be used

Any analysis isn't allowed on the document

From where data/document is obtainable

Saeidnikbakht@kums.ac.ir Taleqani hospital, shahid beheshti Blvd, kermanshah town Tell: 98 83 38357752

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

The request will be assessed and the data would be available in one month.

Comments