Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigating the effect of tenosynovectomy on the Improve the severity of symptoms in patients with carpal tunnel syndrome after open surgery

Protocol summary

Study aim
Investigating the effect of tenosynectomy on the improvement of symptoms and fine movements of fingers in patients with carpal tunnel syndrome after open surgery

Design
A clinical trial with a control group, with parallel groups, a blind strain, block randomization, on 60 patients, for better randomization, web software will be used to prepare a randomization list for both types of treatment in each The block generates random permutations

Settings and conduct
patients referred to the orthopedic clinic and Hazrat Wali Asr Arak Hospital, whose diagnosis of carpal tunnel syndrome was confirmed after examination and confirmation of the diagnosis by an orthopedic specialist. Patients are divided into 2 intervention and control groups, each group containing 30 people diagnosed with carpal tunnel syndrome according to the inclusion criteria, and patients are randomly assigned to the study. In this study, the patient is blinded. The study is of a blind type. Informed consent is obtained from the patient that one of the surgical procedures will be performed without and with tenosinectomy. But in the end, the patient will not understand the type of surgical technique.

Participants/Inclusion and exclusion criteria
confirmation of electrodiagnostic tests, consent to participate in the study, absence of thenar atrophy, absence of old fractures in the forearm and wrist, absence of any congenital deformity in the forearm and wrist area. Exclusion criteria: patient's failure to return, patient's lack of consent to continue the study, patient's lack of cooperation

Intervention groups
Patients with carpal tunnel syndrome undergo tenosinectomy, which means removing the tendon sheath.In the control group, patients undergoing carpal tunnel syndrome surgery are operated without tenosynovectomy, i.e. without removing the tendon sheath.

Main outcome variables
Severity of symptoms, subtle movements of fingers

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190810044492N1**
Registration date: **2023-03-15, 1401/12/24**
Registration timing: **registered_while_recruiting**

Last update: **2023-03-15, 1401/12/24**
Update count: **0**

Registration date
2023-03-15, 1401/12/24

Registrant information

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Name of organization / entity

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-03-01, 1401/12/10

Expected recruitment end date
2023-07-01, 1402/04/10

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of tenosynovectomy on the Improve the severity of symptoms in patients with carpal tunnel syndrome after open surgery

Public title
Investigating the effect of tenosynovectomy on the Improve the severity of symptoms in patients with carpal tunnel syndrome after open surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with carpal tunnel syndrome aged 20 to 70 years Positive electrodiagnostic tests Absence of thenar atrophy The absence of old fractures in the forearm and wrist Absence of any congenital deformity in the forearm and wrist area Absence of rheumatic diseases such as rheumatoid arthritis
Exclusion criteria:
Patient's lack of consent to continue the study Non-cooperation of the patient Failure to visit the patient
Age
From **20 years** old to **70 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, due to the presence of two types of surgical techniques, the block randomization method will be used. The randomization unit is the person. According to the sample size, blocks with a capacity of 4 units were considered. By assigning the letter A to the intervention group and the letter B to the control group, there are six states AABB, BBAA, BABA, ABBA, BAAB and ABAB. Then it is randomly selected from among these situations and a list equal to the sample size is prepared for patients before the start of the study. For better randomization, the web software will be used to prepare the randomization list, which creates random permutations for both types of treatment in each block, and according to the change of permutations in each block, concealment is also observed. During the implementation of the study, the predictability of the treatment for each patient is reduced by the researcher. Site used for random permutation block method: https://www.sealedenvelope.com/simple-randomiser/v1/lists
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, the patient is blinded. The study is of a blind type. Informed consent is obtained from the patient that one of the surgical procedures will be performed without and with tenosinectomy. But in the end, the patient will not understand the type of surgical technique.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Arak University of Medical Sciences
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No. 5, Sardasht Ave., Basij Blvd
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Postal code
3819693345
Approval date
2023-01-08, 1401/10/18
Ethics committee reference number
IR.ARAKMU.REC.1401.306

Health conditions studied

1

Description of health condition studied
carpal tunnel syndrome
ICD-10 code
G56.1
ICD-10 code description
Other lesions of median nerve

Primary outcomes

1

Description
Severity of symptoms
Timepoint
Improvement of the severity of symptoms one day before the operation and one day after the operation and the first week and 3 months after the operation
Method of measurement
Boston Questionnaire (to evaluate the severity of

symptoms and functional status of carpal tunnel syndrome in people) will be used to check the patient's symptoms.

Secondary outcomes

1

Description
Evaluation of the function and fine movements of the fingers
Timepoint
Fine movements and hand function one day before the operation and 3 months after the operation and in terms of improvement of symptoms, one day before the operation and one day after the operation and the first week and 3 months after the operation
Method of measurement
The O'Connor Tweezer Dexterity Test will be used to check fine finger movements. This device is a valid and widely used manual dexterity test. It is used by rehabilitation professionals to assess progress in the recovery of hand and finger function, as well as to assess fine motor skills. The O'Connor Dexterity Test simply requires the user to pick up pins with the provided tweezers and insert them into a series of holes. A high score on this test indicates manual aptitude for tasks that involve the use of small precision tools such as clock assembly.

Intervention groups

1

Description
Intervention group: In this group, carpal tunnel syndrome sufferers will undergo CTS surgery with tenosynovectomy or removal of the tendon sheath (a layer of the membrane around the tendon) and they will be examined for symptoms and subtle movements after the surgery.
Category
Treatment - Surgery

2

Description
Control group: In this group, carpal tunnel syndrome sufferers will undergo CTS surgery without tenosynovectomy or removal of the tendon sheath (a layer of the membrane surrounding the tendon) and will be examined for symptoms and subtle movements after the surgery.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
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Sponsors / Funding sources

1

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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Arak 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
Arak University of Medical Sciences
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Ahmadreza Behruzi

Position
Associate professor

Latest degree
Subspecialist

Other areas of specialty/work
Orthopedics

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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