

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparing the effectiveness of using a drain with not using a drain during surgery in improving the symptoms and satisfaction of patients with bilateral carpal tunnel syndrome.

Protocol summary

Study aim

Comparing the effectiveness of using a drain with not using a drain during surgery in improving the symptoms and satisfaction of patients with bilateral carpal tunnel syndrome.

Design

The clinical trial, controlled, unblinded, with available sampling, on 35 patients with 70 arms. Intervention group: hand of patients who underwent drain placement. Control group: a hand of patients who did not undergo drain implantation.

Settings and conduct

The study population consists of patients with bilateral CTS referring to Shahid Sadoughi and Shahid Rahmon hospitals in Yazd, who are candidates for bilateral surgery. Sampling will be Convenience and then one of the hands that will be randomly selected will undergo drainage during the surgery. It will be placed and the other hand will be operated without inserting a drain. Blinding was not done in this study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with bilateral carpal tunnel syndrome Failure to respond to non-surgical treatment for six months The need for bilateral surgery according to the opinion of the hand surgeon Exclusion criteria: Age below 20 years The patient's inability to cooperate Debilitating upper limb diseases such as rheumatoid arthritis Previous history of hand surgery

Intervention groups

Both hands of patients will undergo surgery. A drain will be placed in one hand after surgery (interventional group), and a drain will not be placed in the other hand (control group)

Main outcome variables

Patients' pain intensity (visual analog scale) Symptom Severity Scale (Boston Questionnaire- SSS Scale) Functional Status Scale (Boston Questionnaire - FSS

Comparison) Grip and Pinch Strength Patient satisfaction with the result of surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230407057839N1**

Registration date: **2023-12-26, 1402/10/05**

Registration timing: **registered_while_recruiting**

Last update: **2023-12-26, 1402/10/05**

Update count: **0**

Registration date

2023-12-26, 1402/10/05

Registrant information

Name

mohammadreza farhadi rad

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 4244 0301

Email address

mohammadreza138999@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2024-09-21, 1403/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of using a drain with not using a drain during surgery in improving the symptoms and satisfaction of patients with bilateral carpal tunnel syndrome.

Public title
The effect of using a drain in the surgery of patients with carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Having bilateral carpal tunnel syndrome (confirmed by history, Phalen examinations, compression test, Electromyography (moderate to severe) failure to respond to non-surgical treatment for six months the need for surgery on both hands (confirmed by a hand surgeon) Consent to participate in the study with knowledge of the objectives of the study
Exclusion criteria:
 Under 20 years of age Lack of necessary cooperation by the patient Conditions that caused upper extremity disability such as rheumatoid arthritis Previous surgery at the carpal tunnel site History of psychiatric diseases (psychosis) and neurological diseases (Parkinson's)

Age
From **20 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **35**

Randomization (investigator's opinion)
Randomized

Randomization description
 Randomization method: simple randomization
 Randomization unit: hand Randomization tool: table of random numbers

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
 Ethics committee of Shahid Sadoughi Yazd University of Medical Sciences
Street address
 No. 1, Prof Hesabi Ave,
City
 Yazd
Province
 Yazd
Postal code
 8915173160
Approval date
 2023-01-19, 1401/10/29
Ethics committee reference number
 IR.SSU.MEDICINE.REC.1402.105

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
 Pain intensity score
Timepoint
 Measurement of VAS criterion before the start of the study, three weeks and 16 weeks after surgery
Method of measurement
 Visual Analogue Scale

2

Description
 Symptom Severity Scale
Timepoint
 Completion of the Boston questionnaire before the start of the study, three weeks and 16 weeks after surgery
Method of measurement
 Boston questionnaire (questions 1 to 11 related to the severity of symptoms)

Secondary outcomes

1

Description
 palmar grip &pulp (fingertip) pinch
Timepoint
 Perform palmar grip &pulp (fingertip) pinch test before the start of the study, three weeks and 16 weeks after

surgery
Method of measurement
Pinch meter and palmar grip dynamometer

2

Description
Functional Status Scale
Timepoint
Completion of the Boston questionnaire before the start of the study, three weeks and 16 weeks after surgery
Method of measurement
Boston Questionnaire (questions 12 to 19 related to function)

Intervention groups

1

Description
Intervention group: The hand of the patient who is placed under a drain after carpal tunnel syndrome surgery
Category
Treatment - Surgery

2

Description
Control group: The hand of patients who do not undergo drainage after carpal tunnel syndrome surgery
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Abbas Abdoli Tafti
Street address
No. 1, Prof. Hesabi Ave.
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Yazd
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8915173160
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mohammadreza138999@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Abas Abdoli
Street address
No, 1. Prof Hesabi Ave,
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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
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Mohammad Reza Farhadi Rad
Position
resident
Latest degree
Specialist
Other areas of specialty/work
Orthopedics
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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mohammad Reza Farhadi Rad

Position

resident

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

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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