Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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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mohammadreza138999@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Abas Abdoli

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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
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Latest degree
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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