

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of satisfaction, performance and pain in patients undergoing carpal tunnel syndrome surgery with skin repair using two simple and subcuticular methods

Protocol summary

Study aim

This study's aim is to compare satisfaction, performance and pain in patients undergoing carpal tunnel syndrome surgery with skin repair using two simple and subcuticular methods. The practical aim is to achieve a suitable suturing method with minimum scar and pain and maximum satisfaction.

Design

Two arm parallel group interventional clinical trial

Settings and conduct

Patients who have been diagnosed with bilateral CTS are examined by an orthopedic surgeon at the Besat Hospital. After prep and drape in sterile conditions and under proper anesthesia with tourniquet control with open technique MINI-PALM carpal tunnel release is performed. the skin of one hand is repaired with a single interrupted method, and the other hand is repaired with a continuous subcuticular method, both using Non-absorbable 3-0 nylon.

Participants/Inclusion and exclusion criteria

The participants include all patients over 18 years of age who referred to Besat Hospital in Hamedan with the diagnosis of severe or moderate bilateral CTS. The conditions of non-entry include: the severity of CTS is different in both hands according to clinical criteria and NCV-EMG; The onset of symptoms for each hand is more than 10 months; CTS has developed in the context of inflammatory diseases; history of psychiatric diseases; history of skin diseases; having diseases affecting blood vessels and peripheral nerves.

Intervention groups

Surgery is performed simultaneously on both hands in all patients. One hand is repaired with single interrupted method, and the other hand is repaired with continuous subcuticular method. an orthopedic surgeon visits patients In weeks 2, 6, and 12, and BCTQ, POSAS, and VAS questionnaires are filled for each hand separately.

The sutures are removed in the second week for both hands.

Main outcome variables

Satisfaction; performance; pain score; scar score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231121060126N1**

Registration date: **2023-11-29, 1402/09/08**

Registration timing: **registered_while_recruiting**

Last update: **2023-11-29, 1402/09/08**

Update count: **0**

Registration date

2023-11-29, 1402/09/08

Registrant information

Name

Asrin Moradi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3461 3439

Email address

asrin1997@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-29, 1402/09/08

Expected recruitment end date

2023-12-09, 1402/09/18

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of satisfaction, performance and pain in patients undergoing carpal tunnel syndrome surgery with skin repair using two simple and subcuticular methods

Public title
Comparison of two skin repair methods in carpal tunnel syndrome surgery

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
All patients over 18 years old with a diagnosis of severe or moderate bilateral Carpal Tunnel Syndrome
Exclusion criteria:
The severity of carpal tunnel syndrome is different bilaterally according to clinical criteria and EMG-NCV The onset of symptoms for each hand is more than 10 months Carpal tunnel syndrome is caused by inflammatory diseases such as rheumatoid arthritis History of psychiatric diseases such as depression History of skin diseases The existence of diseases involving blood vessels and peripheral nerves such as diabetes Age less than 18 years

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **42**
More than 1 sample in each individual
Number of samples in each individual: **2**
Patient's right and left hand

Randomization (investigator's opinion)
N/A

Randomization description

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 Hamedan University of Medical Sciences
Street address
Shahid Fahmideh Blvd., Hamedan University of Medical Sciences, fourth floor
City
Hamedan
Province
Hamadan
Postal code
6517838678
Approval date
2023-11-29, 1402/09/08
Ethics committee reference number
IR.UMSHA.REC.1402.556

Health conditions studied

1

Description of health condition studied
Carpal Tunnel Syndrome
ICD-10 code
G56
ICD-10 code description
Mononeuropathies of upper limb

Primary outcomes

1

Description
Satisfaction and performance score in BCTQ questionnaire
Timepoint
Filling the BCTQ questionnaire in 2, 6, 12 weeks after Carpal Tunnel Release Surgery
Method of measurement
BCTQ questionnaire

2

Description
Scar score in POSAS questionnaire
Timepoint
Filling the POSAS questionnaire in 2, 6, 12 weeks after Carpal Tunnel Release Surgery
Method of measurement
POSAS questionnaire

3

Description
Pain score in VAS questionnaire
Timepoint
Filling the VAS questionnaire in 2, 6, 12 weeks after Carpal Tunnel Release Surgery
Method of measurement
VAS questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Repair of patients' right hand surgical incision by simple suture method with non-absorbable 3-0 nylon

Category

Treatment - Surgery

2

Description

Intervention group 2: Repair of patients' left hand surgical incision by subcuticular suture method with non-absorbable 3-0 nylon

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Besat hospital in Hamedan

Full name of responsible person

Sepehr Shirouei

Street address

Besat hospital, Shahid Beheshti Blvd.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

Full name of responsible person

Reza Shokouhi

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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

Hamedan 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

Hamedan University of Medical Sciences

Full name of responsible person

Asrin Moradi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

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Position

Student

Latest degree

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Person responsible for updating data

Contact

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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

There is no further information

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