

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Comparison between the scar of open carpal tunnel release closure with simple and horizontal mattress sutures

Protocol summary

Study aim

The comparison between scar of simple and horizontal mattress sutures in open carpal tunnel release

Design

In this study, a randomized controlled clinical trial with parallel groups, double-blind, in phase 2 of the clinical trial, 42 patients with a definitive diagnosis of carpal tunnel syndrome, which was affiliated to the orthopedic clinic of Rasoul Akram Hospital from the beginning of October 2020 to the beginning of October 2021. Then patients will be randomly assigned to the two groups with a ratio of 1: 1 to two groups by random block method using random allocation software. Group 1 will include patients whose surgical incision is closed with a simple suture and group 2 will include patients whose surgical incision is closed with a horizontal suture.

Settings and conduct

In this study, 42 patients with a definitive diagnosis of carpal tunnel syndrome who will be referred to the Rasool Akram Hospital were randomly divided into two groups. Patients' surgery will be performed in an orthopedic operating room and each patient will have a type of haircut. Patients' wound follow-up will be performed in the 12th week after surgery, and a specialist examining the patient's wound will measure the thickness and height of the skin surface, and blinding for the type of suture will be performed for the specialist and patients.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1. Patients with a definitive diagnosis of carpal tunnel syndrome 2. Age 18 to 80 years 3. Conscious consent to participate in the study Exclusion criteria: 1. Patients with a positive history of median nerve open surgery 2. Conscious dissatisfaction

Intervention groups

Intervention group: patient that their incisions will be closed with simple sutures control group: patient that their incisions will be closed with horizontal mattress sutures

Main outcome variables

Height of the scar Width of the scar

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200115046149N1**

Registration date: **2020-11-24, 1399/09/04**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-24, 1399/09/04**

Update count: **0**

Registration date

2020-11-24, 1399/09/04

Registrant information

Name

naseh sileymani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2264

Email address

dr.sileymani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-09-23, 1400/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the scar of open carpal tunnel release closure with simple and horizontal mattress sutures

Public title

Comparison of scar of simple and horizontal mattress suture in open CTR

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with carpal tunnel syndrome who are first-time candidates for surgery

Exclusion criteria:

Previous open carpal tunnel release on the same side
History of other surgeries on hand

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **42**

More than 1 sample in each individual

Number of samples in each individual: **21**

Each hand could be a sample

Randomization (investigator's opinion)

Randomized

Randomization description

Random sequence generation software in addition to simple randomization capable of the sequential generation they are randomized by the block making method. Allocation of patients will be done randomly and by random block method using Random Allocation statistical software. Software inputs will include the total number of samples and the number of treatment groups (intervention and control). Then, after selecting the Generate random list option, the Equal Size option is selected from the Options section of the blocks section and the number of blocks is entered. The software output will be in Html or text files format and will include random numbers assigned to two groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients will be divided in 2 groups in a randomized manner and the follow up examiners will not be informed about type of sutures

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Tehran, Hemmat Highway next to Milad Tower, Iran
University of Medical Sciences

City

Tehran

Province

Tehran

Postal code

۱۳۴۹۶۱۴۵۳۵

Approval date

2020-11-04, 1399/08/14

Ethics committee reference number

IR.IUMS.FMD.REC.1399. 466

Health conditions studied

1

Description of health condition studied

Carpal tunnel syndrome

ICD-10 code

G56.00

ICD-10 code description

Carpal tunnel syndrome, unspecified upper limb

Primary outcomes

1

Description

Height of scar, width of scar

Timepoint

12 weeks after surgery

Method of measurement

Collis

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: closing of the surgical incision with simple sutures

Category

Treatment - Surgery

2

Description

Intervention group: closing of the surgical incision with horizontal mattress sutures

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasool akram hospital

Full name of responsible person

Naseh sileymani

Street address

Hashemi rafsanjani ave. Sattarkhan blvd

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1445613131

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+98 21 6435 2264

Email

Dr.sileymani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

سيد عباس متوليان

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Tehran, Hemmat Highway next to Milad Tower, Iran
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Email

research-m@iums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Naseh Sileymani

Position

Orthopedist

Latest degree

Medical doctor

Other areas of specialty/work

Orthopedics

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Person responsible for scientific inquiries

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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

To observe the ethical principle and to observe the confidentiality of patients' information.

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can potentially be shared after unidentified individuals, or only part of the data, such as information about the main outcome or the like, can be shared.

When the data will become available and for how long

Access started from the beginning of 2022

To whom data/document is available

Researchers in this field

Under which criteria data/document could be used

To improve treatment methods

From where data/document is obtainable

Tehran, Nyaesh Ave, Rasoul Akram Hospital, Dr. Naseh Hosseini, Email: dr.sieymani@gmail.com

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

Request to the corresponding author

Comments