Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A randomized controlled trial comparing three methods of skin repair with nylon, prolene and monocryl threads after carpal tunnel release surgery

Protocol summary

Study aim
Comparison of skin repair using different types of sutures in carpal tunnel syndrome surgery

Design
Clinical trial with parallel groups, double-blind, randomized, phase 2 on 93 patients

Settings and conduct
This information was requested by randomized clinical trial method. In this study, patients are divided into three groups. The first group has surgical incision repair with 4-0 monocryl suture, the second group has repair with 4-0 nylon suture, and the third group has repair with 4-0 prolene suture. In all three groups, the repair is performed with continuous and subcuticular suture. All patients are dressed in a similar way and refer for follow-up at 2 and 6 weeks after surgery. Wound assessment is performed in all three groups at the first post-op visit. Sutures are removed in the nylon and prolene group at the first post-op visit. All patients are evaluated by the POSAS questionnaire at the first and second post-op visits. The above variables are recorded separately in both groups at the second and sixth weeks after surgery, and the findings are analyzed in the software environment.

Participants/Inclusion and exclusion criteria
The inclusion criteria for the study included all patients with carpal tunnel syndrome who underwent surgery

Intervention groups
In this study, one of 3 types of threads, monocryl, nylon or prolene is used randomly for skin repair

Main outcome variables
The main outcome of this study is to find the best thread to reduce pain and scarring at the surgical site of patients.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250315065078N1**
Registration date: **2025-06-04, 1404/03/14**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-04, 1404/03/14**
Update count: **0**

Registration date
2025-06-04, 1404/03/14

Registrant information

Name
Milad Najafi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 938 279 6698

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najafimilad4731@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-03-21, 1404/01/01

Expected recruitment end date
2026-03-21, 1405/01/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A randomized controlled trial comparing three methods of skin repair with nylon, prolene and monocryl threads after carpal tunnel release surgery

Public title
Comparison of skin repair with different types of sutures in carpal tunnel syndrome

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All patients with carpal tunnel syndrome who undergo surgery

Exclusion criteria:

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **93**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, we will use the Restricted Randomization method of Block Randomization. Blocking is usually used to balance the number of samples allocated to each of the study groups. The size of all blocks is equal and in this trial we will have three groups of 9 blocks of nine (including 3 participants from each group) and 2 groups of six (including 3 participants from each group). Then, in order to randomly select the generated blocks, random number generation software such as the R language will be used and 12 numbers will be randomly generated from 1 to 12 to select the blocks.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this study, only the treating physician is aware of the type of suture used, and the patient is unaware of the type of suture used. Postoperative evaluation of patients is performed by a trained evaluator who has no role in the treatment of the patients, is unaware of the division of patients into different groups, and is unaware of the type of suture used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences

Street address
otagh 6103 Engelab Square, North Kargar Street, Borhani Alley, Engelab 6 Dormitory, Room 6103

City
Tehran

Province
Tehran

Postal code
6761964558

Approval date
2025-03-21, 1404/01/01

Ethics committee reference number
IR.TUMS.IKHC.REC.1403.570

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
Scarring rate in skin repair after carpal tunnel syndrome surgery

Timepoint
View of the surgical scar 2 and 6 weeks later

Method of measurement
Observation and examination of the surgical site

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with carpal tunnel syndrome who undergo surgery will be divided into 3 groups, and each group will be repaired randomly with monocryl, nylon, or prolene sutures

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Hospital Complex
Full name of responsible person
Aydin Arabzadeh
Street address
Keshavarz Boulevard, Gharib Street
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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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
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Aydin Arabzadeh
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Orthopedics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Title and more details about the data/document
Only information related to the main outcome can be shared
When the data will become available and for how long
After the publication of the results
To whom data/document is available
Scientific and academic institutions
Under which criteria data/document could be used
Provided that the personal information of patients is not disclosed
From where data/document is obtainable
Refer to email address
What processes are involved for a request to access data/document
You can access information by visiting your email
Comments