Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of surgical site closure with Monocrly Vs. Nylon sutures on the incidence, severity, and duration of pillar pain and surgical site scar in patients with carpal tunnel syndrome

Protocol summary

Study aim

The aim of this study is to compare the effect of using Monocryl Vs. Nylon sutures for surgical site closure on the incidence, severity, and duration of pillar pain, as well as scar quality in patients undergoing carpal tunnel release surgery.

Design

Randomized, controlled clinical trial with two parallel arms (Monocryl group and Nylon group), double-blinded; the total sample size is 70 patients (35 per arm). randomization will be performed using the EAND function in Excel software.

Settings and conduct

Study setting: Plastic surgery department of 15th khordad hospital, Tehran; Study population: patients with carpal tunnel syndrome undergoing standard surgery; Blinding: this is a double-blinded study; The patient as well as the individual responsible for postoperative visits, data recording, and statistical analysis are fully blinded to the allocated groups; The surgeon remains unaware of the suture type until the final skin closure to ensure identical technique.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients candidate for carpal tunnel release surgery; providing informed consent; Exclusion criteria : Age under 18; diabetes mellitus; systemic diseases affecting wound healing; history of trauma or fracture in the affected hand; recurrent cases of the disease.

Intervention groups

Intervention group: surgical site closure using 4-0 Monocryl suture in a subcuticular fashion; Control group: surgical site closure using 4-0 Nylon suture in a subcuticular fashion; other surgical steps are identical in both groups.

Main outcome variables

Incidence of pillar pain; severity of pillar pain; duration of pillar pain; surgical site scar quality; all will be measured after the surgery.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260309068977N2**
Registration date: **2026-05-12, 1405/02/22**
Registration timing: **registered_while_recruiting**

Last update: **2026-05-12, 1405/02/22**
Update count: **0**

Registration date

2026-05-12, 1405/02/22

Registrant information

Name

soraya shahrokh shahraki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8890 1108

Email address

golbahar.shahraki@sbmu.ac.ir

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-03-01, 1404/12/10

Expected recruitment end date

2026-12-21, 1405/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of surgical site closure with Monocrly Vs. Nylon sutures on the incidence, severity, and duration of pillar pain and surgical site scar in patients with carpal tunnel syndrome

Public title

Comparison of monocryl and nylon suture in CTR surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with a confirmed diagnosis of carpal tunnel syndrome patients who are candidates for standard carpal tunnel release surgery Patients who have provided written informed consent to participate in the study

Exclusion criteria:

Age under 18 years or individuals unable to make decision and provide informed consent Individuals with diabetes mellitus Individuals with systemic diseases affecting wound healing, such as collagen vascular diseases Individuals with a history of fracture or extensive soft tissue injury in the hand affected by carpal tunnel syndrome Individuals consuming chemotherapy drugs or corticosteroids individuals with recurrent carpal tunnel syndrome

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization will be performed in this study. The random sequence will be generated using the RAND function in Microsoft Excel software by an individual not involved in the surgical team. to ensure allocation concealment, sequentially numbered, opaque, sealed envelopes will be used; the intervention type for each patient will be revealed only in the operating room after the envelope is opened by a surgical assistant.

Blinding (investigator's opinion)

Double blinded

Blinding description

At the end of the operation, exactly before closing the surgical site, the surgeon is informed of the type of suture to be used for the patient. In this way, the surgical technique will be identical in all patients. All postoperative visits, data recording, and data analysis are performed by someone who is unaware of the study's objectives and the groupings.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

15th Khordad hospital, Shaid Azodi Street

City

Tehran

Province

Tehran

Postal code

1598763513

Approval date

2026-02-24, 1404/12/05

Ethics committee reference number

IR.SBMU.MSP.REC.1404.795

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

Prevalence, severity and duration of Pillar pain

Timepoint

1,6,12,24 weeks post operation

Method of measurement

Visual analogue scale (VAS)

Secondary outcomes

1

Description

Surgical site Scar quality

Timepoint

1, 6, 12 and 24 weeks post operation

Method of measurement

Vancouver scar scale (VSS)

Intervention groups

1

Description

Intervention group: Open (standard) carpal tunnel release surgical site closure using 4-0 Monocryl suture (manufactured by Ethicon, USA) in a subcuticular manner.

Category

Treatment - Surgery

2

Description

Control group: Open (standard) carpal tunnel release surgical site closure using 4-0 Nylon suture (manufactured by Supa, Iran) in a subcuticular manner.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Plastic surgery 15th Khordad Hospital in Tehran

Full name of responsible person

Muhammad Hossein Baqeri Pour

Street address

Shshid Azodi street

City

Tehran

Province

Tehran

Postal code

1598763513

Phone

+98 21 8894 3434

Email

15khordad@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Afshin Zarghi

Street address

Headquarters of Shihid Beheshti university of Medical Sciences, Shahid Arabi Street, Yemen Street, Shaid Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

vcresearch@sbmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohamad Hossein Baqeri pour

Position

Plastic surgery resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

15th khordad Hospital, Shahid Azodi Street

City

Tehran

Province

Tehran

Postal code

1598763513

Phone

+98 21 8894 3434

Email

graypackage@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohamad Hossein Baqeri pour

Position

Plastic surgery resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

15th khordad Hospital, Shahid Azodi Street

City

Tehran

Province

Tehran

Postal code

1598763513

Phone

+98 21 8894 3434

Email

graypackage@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Mohamad Hossein Baqeri pour

Position

Plastic surgery resident

Latest degree

Specialist

Other areas of specialty/work

General Surgery

Street address

15th khordad Hospital, Shahid Azodi Street

City

Tehran

Province

Tehran

Postal code

1598763513

Phone

+98 21 8894 3434

Email

graypackage@gmail.com

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