Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of Skin Closure Techniques in Carpal Tunnel Release: A Randomized Controlled Trial Assessing Postoperative Pillar Pain and Scar Quality

Protocol summary

Study aim

The main aim of this study is to compare two skin closure techniques—subcuticular Monocryl sutures and interrupted Nylon sutures—and their effects on the severity of pillar pain after open carpal tunnel release surgery. Secondary aims include assessing pillar pain using the Visual Analogue Scale (VAS) and evaluating scar quality with the Patient and Observer Scar Assessment Scale (POSAS) at 2 weeks, 6 weeks, and 3 months postoperatively. Ultimately, this study seeks to determine the most effective suture material for skin closure to help reduce pain and complications, enhance patients' quality of life, and lower treatment costs.

Design

This phase 2 double-blind RCT includes 128 patients randomized into parallel groups using computer-generated block randomization (blocks of 4, 6, and 8). Allocation is concealed via sealed, opaque, sequentially numbered envelopes.

Settings and conduct

This prospective double-blinded study at Imam Khomeini Hospital will compare Monocryl and Nylon sutures in open carpal tunnel release. Outcomes will be evaluated at 2, 6, and 12 weeks using VAS and POSAS.

Participants/Inclusion and exclusion criteria

Patients aged 18 years and older scheduled for carpal tunnel release will be eligible for inclusion. Exclusion criteria are patients younger than 18, pregnant individuals, those with cognitive or communication impairments, patients undergoing additional procedures, those who withdraw consent, cancel surgery, or fail to comply with the postoperative protocol.

Intervention groups

Intervention 1: Skin closure using continuous subcuticular absorbable Monocryl 4-0 sutures
Intervention 2 (Control Group): Skin closure using interrupted non-absorbable Nylon 4-0 sutures

Main outcome variables

Pillar pain (VAS) at 2, 6, and 12 weeks; Scar quality (POSAS) at 2, 6, and 12 weeks

General information

Reason for update

Due to the potential risk of selection bias in the initial implementation method of the study, the research team, after expert review, decided to conduct the study using a randomized design in order to minimize any possible bias and enhance the validity of the results

Acronym

IRCT registration information

IRCT registration number: **IRCT20250501065557N1**
Registration date: **2025-05-20, 1404/02/30**
Registration timing: **prospective**

Last update: **2025-06-10, 1404/03/20**
Update count: **1**

Registration date

2025-05-20, 1404/02/30

Registrant information

Name

Hamed Naghizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2025-11-22, 1404/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Skin Closure Techniques in Carpal Tunnel Release: A Randomized Controlled Trial Assessing Postoperative Pillar Pain and Scar Quality

Public title

Pillar Pain After Carpal Tunnel Release

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients over 18 years old scheduled for carpal tunnel surgery

Exclusion criteria:

Patients under 18 years of age Pregnant individuals Unable to provide reliable postoperative feedback due to cognitive or communication limitations Patients scheduled for concurrent procedures such as trigger finger or cubital tunnel release Individuals who declined to participate Those whose surgeries were canceled or not scheduled Patients excluded due to enrollment or protocol deviations

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, block randomization with variable block sizes (4, 6, and 8) will be performed using a computer-generated random sequence. This method is designed to ensure balanced allocation of participants across the two groups while minimizing the predictability of the assignment sequence. The unit of randomization is the individual, and each participant will be independently assigned to one of the two study groups. To cover the total sample size of 128 participants, a total of 23 blocks will be used, consisting of 11 blocks of size 4, 6 blocks of size 6, and 6 blocks of size 8. Within each block, participants will be allocated equally and randomly to the two groups. The randomization sequence will be generated using R statistical software by an independent research coordinator who is not involved in patient recruitment or outcome assessment. To ensure allocation concealment, sequentially numbered, sealed, opaque envelopes will be used. Each envelope will be opened by the investigator only after the patient meets the eligibility criteria and is formally enrolled in the study. This procedure is intended to prevent allocation bias and to preserve the internal validity of the trial.

Blinding (investigator's opinion)

Double blinded

Blinding description

All postoperative assessments were performed by a single trained evaluator who was independent of the surgical team and had no involvement in any part of the surgical procedure. The evaluator was unaware of group allocation at the time of patient enrollment, and the patients were also blinded to their assigned group. Thus, the study was conducted in a double-blinded manner to minimize assessment and performance bias.

Placebo

Not used

Assignment

Parallel

Other design features

This study possesses several unique design features. First, a double-blinded assessment protocol was employed: patients were unaware of their group allocation, and the postoperative outcome assessor was blinded to group assignment and remained completely independent of the surgical team. Second, the study utilized a culturally adapted and psychometrically validated Persian version of the Patient and Observer Scar Assessment Scale (POSAS), ensuring reliable and standardized scar evaluation for the target population. Third, all surgical procedures were performed by a single fellowship-trained hand surgeon, which minimized variability in surgical technique. Fourth, the study compared two distinct yet commonly used skin closure methods—subcuticular absorbable Monocryl sutures and interrupted non-absorbable Nylon sutures—allowing for a meaningful evaluation of the impact of suture type on postoperative outcomes

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of TEHRAN University of Medical Sciences

Street address

Forsat Shirazi

City

Tehran

Province

Tehran

Postal code

1419933813

Approval date
2024-12-04, 1403/09/14
Ethics committee reference number
IR.TUMS.IKHC.REC.1403.167

Health conditions studied

1

Description of health condition studied
Pillar pain after carpal tunnel release
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pillar pain, defined as pain in the thenar and hypothenar regions following open carpal tunnel release, will be assessed using the Visual Analogue Scale (VAS), ranging from 0 (no pain) to 10 (worst possible pain). Scar quality will be evaluated using the Patient and Observer Scar Assessment Scale (POSAS), which includes two components. The Patient Scale consists of six items—pain, itching, color, stiffness, thickness, and irregularity—each scored from 1 (similar to normal skin) to 10 (worst condition). The Observer Scale also includes six items—vascularity, pigmentation, thickness, relief, pliability, and surface area—scored on the same scale. Higher total scores in both scales indicate poorer scar quality.
Timepoint
2 weeks postoperatively - 6 weeks postoperatively - 3 months (12 weeks) postoperatively
Method of measurement
Pillar pain, defined as pain in the thenar and hypothenar regions following open carpal tunnel release, will be assessed using the Visual Analogue Scale (VAS), ranging from 0 (no pain) to 10 (worst possible pain). Scar quality will be evaluated using the Patient and Observer Scar Assessment Scale (POSAS), which includes two components. The Patient Scale consists of six items—pain, itching, color, stiffness, thickness, and irregularity—each scored from 1 (similar to normal skin) to 10 (worst condition). The Observer Scale also includes six items—vascularity, pigmentation, thickness, relief, pliability, and surface area—scored on the same scale. Higher total scores in both scales indicate poorer scar quality.

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group, skin closure will be performed using continuous subcuticular suturing with 4-0 absorbable Monocryl following open carpal tunnel release. This technique involves placing the suture beneath the skin surface, eliminating the need for removal during follow-up. All procedures in this group will be carried out under standardized conditions by a fellowship-trained hand surgeon, following the same postoperative care protocol as the control group.
Category
Treatment - Surgery

2

Description
Control group: In the control group, skin closure will be performed using non-absorbable 4-0 Nylon sutures applied with an interrupted vertical mattress technique following open carpal tunnel release. These sutures will be removed at the first postoperative visit. All surgeries in this group will also be performed under standardized conditions by a fellowship-trained hand surgeon, following the same postoperative care protocol as the intervention group.
Category
Treatment - Surgery

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital, Tehran
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
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Full name of responsible person
Naghizadeh
Position
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Person responsible for updating data

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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
Due to ethical considerations, concerns about participant confidentiality, and the lack of an established secure data-sharing infrastructure, there is currently no plan to share individual participant data.
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
Yes - There is 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

Full Study Protocol Final Clinical Study Report These documents will be provided as supplementary files to the main article or through appropriate repositories, depending on the journal's policy. It should be noted that no raw data or individual-level participant information will be shared separately. All data will be presented only in an anonymized, aggregated, and analyzed form within the published report and article, in order to maintain participant confidentiality and data protection.

When the data will become available and for how long

Access to the study protocol and the final clinical study report will begin 6 months after publication of the final study results in a peer-reviewed journal. These documents will be made available as supplementary files or through public repositories associated with the journal. Once shared, access will remain open and unrestricted.

To whom data/document is available

The shared documents, including the study protocol and final clinical report, will be publicly available as part of the article supplement or through scientific repositories and will not require a formal request. If additional data access is requested in the future, only researchers affiliated with academic institutions, licensed research centers, or recognized healthcare organizations will be eligible to apply. Requests from industry professionals may also be considered if accompanied by a clear research objective and appropriate ethics approval.

Under which criteria data/document could be used

To access de-identified individual-level data or other study-related documents, the following conditions must be met: *Conditions for Use of Data and Documents: 1-Data and documents may only be used for clearly defined, scientifically valid research purposes. 2-All analyses must be conducted within the scope of the approved research proposal. 3-Commercial, promotional, or political use of the data or documents is strictly prohibited. 4-Any publication resulting from the shared data must include proper citation of the original study and prior notification to the original research team. 5-The recipient must agree not to share the data with third parties and to use the data strictly within the approved scope. *Requirements for Submitting an Access Request: 1-A formal written request including full applicant information and institutional affiliation. 2-A clear and specific research proposal outlining objectives, methodology, and the type of data required. 3-An official ethics committee approval (IRB approval) for secondary use of the data. 4-A signed Data Use Agreement committing to confidentiality, non-redistribution, and appropriate use of the data.

From where data/document is obtainable

In case of a formal request for access to anonymized individual-level data or study documents, the following conditions must be met: Submission of a formal written request including the applicant's full details and institutional affiliation (preferably academic, clinical, or research-based). Provision of a clear research proposal outlining the intended use of the data/documents. Ethics committee approval for the proposed secondary analysis. Signing of a Data Use Agreement (DUA) that includes commitments to: not attempt re-identification of individuals, not share data with third parties, use the data solely for approved research purposes. Permitted analyses must align with the objectives outlined in the request. Commercial use, promotional purposes, or publication without prior approval are strictly prohibited. All requests will be reviewed internally and, if approved, limited access will be granted under the defined terms.

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

If access to study documents (e.g., study protocol or final report) or de-identified individual-level data is considered, the following process applies: Submission of a formal written request, including applicant details, institutional affiliation, purpose of use, and specific documents or data requested. Initial review by the research team within 2 weeks of receiving the request. Upon preliminary approval, the applicant must: Submit a relevant research proposal. Provide IRB/Ethics Committee approval. Sign a Data Use Agreement (DUA) outlining permitted uses and data protection commitments. Following full review and signed agreement, approved documents or data will be provided within 4 weeks of the initial request. Estimated total processing time: 4 to 6 weeks from complete request submission to data/document delivery.

Comments