Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of Carpal Tunnel Release Surgery with Hypothenar fat Pad Flap for the Treatment of Carpal Tunnel Syndrome

Protocol summary

Study aim

A Comparative Study of Carpal Tunnel Release Alone Versus Carpal Tunnel Release Combined with Hypothenar Fat Pad Flap in the Management of Carpal Tunnel Syndrome

Design

This is a single-blind randomized clinical trial. Patients were randomly allocated to two treatment groups. Assessments were performed at weeks 2, 4, and 12 post-intervention by a blinded evaluator.

Settings and conduct

This study is a prospective interventional trial on patients with Carpal Tunnel Syndrome (CTS), conducted in 2025 at a private orthopedic clinic in Shahrood County. Intervention Group 1: Carpal Tunnel Release (CTR) only Intervention Group 2: CTR with Hypothenar Fat Pad Flap (HFPF) Group assignment was performed manually using a random number table. The clinical evaluator and data analyst were blinded to the group allocation, while patients and surgeons were not blinded. Blinding: Clinical evaluator and data analyst: Blinded (single-blind)

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Confirmed CTS diagnosis Age ≥ 18 years Informed consent Clinical symptoms (numbness, tingling, weakness) Exclusion Criteria: History of wrist surgery or nerve reconstruction Systemic diseases mimicking CTS Recent hand/wrist injury (past 6 months) Use of medications affecting peripheral nerves

Intervention groups

Patients were randomly assigned to two equal groups: Group 1 received Carpal Tunnel Release (CTR). Group 2 received CTR plus Hypothenar Fat Pad Flap (CTR+HFPF)

Main outcome variables

Boston Questionnaire scores, grip/pinch strength, two-point discrimination, Phalen and Tinel tests, and EMG/NCV parameters were measured at weeks 2, 4, and 12 to assess treatment efficacy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250722066599N1**
Registration date: **2025-10-24, 1404/08/02**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-24, 1404/08/02**
Update count: **0**

Registration date

2025-10-24, 1404/08/02

Registrant information

Name

Mohammad Vazifeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-10-23, 1404/08/01

Expected recruitment end date

2026-01-21, 1404/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Carpal Tunnel Release Surgery with Hypothenar fat Pad Flap for the Treatment of Carpal Tunnel Syndrome

Public title
Comparison of two Surgical Techniques for Carpal Tunnel Syndrome : Standard vs. Advanced Procedures

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Definitive diagnosis of Carpal Tunnel Syndrome (CTS) based on clinical and electrodiagnostic criteria.Definition of Carpal Tunnel Syndrome (CTS):CTS is a compressive neuropathy caused by compression of the median nerve within the carpal tunnel of the wrist, presenting with sensory and motor symptoms in the hand. Diagnosis is based on a combination of clinical findings and electrodiagnostic confirmation. Age ≥ 18 years. Age<65 years Informed consent for participation in the study. Presence of clinical symptoms such as numbness, tingling, or weakness in the affected hand.

Exclusion criteria:
History of wrist surgery or nerve reconstruction in the affected hand. Systemic diseases that may mimic CTS symptoms (e.g., uncontrolled diabetes, thyroid disorders). Recent hand or wrist injury within the past 6 months. Use of medications affecting peripheral nerves.

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
After selecting 40 eligible patients based on the inclusion criteria, each patient was assigned a unique identification number. For randomization, a random number table was prepared, and patients were reviewed one by one according to their identification numbers. Using the numbers drawn from the table, each patient was randomly assigned to one of the two groups (CTR or CTR+HFPF). This procedure was carried out by an individual independent of the treatment team to ensure allocation concealment and to prevent any selection bias. All assigned numbers and the order of assignment were recorded and preserved, allowing verification that the allocation was indeed random by a knowledgeable observer. Although statistical software or online randomization tools could have been used, in this study, a manual and traceable random number table method was applied

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, due to the surgical nature of the wrist intervention, patients and surgeons were not blinded and therefore were aware of the treatment group. However, to minimize bias, the following measures were implemented: 1. Clinical assessments and data collection were performed by an independent evaluator who was unaware of patients' group allocation. 2. Statistical analyses were conducted by an independent analyst blinded to the treatment assignment. 3. Patients completed the Boston questionnaires without knowledge of the specific aim of the treatment comparison, reducing expectancy effects. Therefore, the study was single-blind: the clinical evaluator and the data analyst were blinded, but patients and surgeons were not. Answer for the questionnaire about who was blinded: Patients: No Surgeons: No Clinical evaluator: Yes Data analyst: Yes

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of islamic azad University of shahrood

Street address
hesabi avenue

City
shahrood

Province
Semnan

Postal code
7157759318

Approval date
2023-12-29, 1402/10/08

Ethics committee reference number
IR.IAU.SHAHROOD.REC1402.108

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
Improvement in symptom severity and functional status : based on the Boston Carpal Tunnel Questionnaire (BCTQ). This outcome evaluates the degree of symptom relief (such as numbness, tingling, nocturnal pain, and hand weakness) and the patient's ability to perform daily tasks (such as writing, buttoning, and holding objects). The BCTQ provides a validated and quantitative assessment of both symptom severity (SSS) and functional status (FSS).

Timepoint
4, 8, and 12 weeks after intervention.

Method of measurement
Using the BCTQ, which includes 19 questions divided into two subscales (SSS and FSS). Each item is rated on a 5-point Likert scale, and lower scores indicate better symptom control and hand function.

Secondary outcomes

1

Description
Reduction in pain : intensity as an indicator of symptomatic improvement following surgery. Pain relief is a key determinant of patient satisfaction and surgical success in carpal tunnel syndrome management.

Timepoint
2, 4, 8, and 12 weeks after intervention.

Method of measurement
Using the Visual Analog Scale (VAS), where patients mark their pain intensity on a 10 cm horizontal line ranging from 0 (no pain) to 10 (worst imaginable pain).

2

Description
Improvement in sensory function of the hand . Restoration of sensory discrimination is essential for hand dexterity and fine motor control.

Timepoint
2, 4, 8, and 12 weeks after intervention.

Method of measurement
Assessed using the Two-Point Discrimination (2PD) test with a calibrated caliper. The minimum distance (in millimeters) at which the patient can distinguish two separate points is recorded.

3

Description
Improvement in neurological clinical tests , including Phalen and Tinel tests, reflecting recovery of median nerve function.

Timepoint
2, 4, 8, and 12 weeks after intervention.

Method of measurement
Clinical assessment performed by the investigator; results documented as positive or negative for each test.

4

Description
Increase in hand muscle strength , including grip and pinch strength, as an indicator of motor recovery and functional improvement.

Timepoint
2, 4, 8, and 12 weeks after intervention.

Method of measurement
Measured using a hand dynamometer (in kilograms) for grip strength and a pinch gauge for pinch strength. Higher readings indicate better motor recovery.

Intervention groups

1

Description
Conventional Carpal Tunnel Release (CTR): Patients assigned to this group will undergo standard open carpal tunnel release surgery. Under local anesthesia and sterile conditions, a longitudinal incision (approximately 3–4 cm) will be made along the radial border of the ring finger at the base of the palm. The subcutaneous tissues and palmar fascia will be carefully dissected to expose the transverse carpal ligament, which will then be completely divided to decompress the median nerve. Hemostasis will be achieved, and the wound will be closed with interrupted nylon sutures.

Category
Treatment - Surgery

2

Description
Carpal Tunnel Release with Hypothenar Fat Pad Flap (HFPF): After standard carpal tunnel release, a vascularized adipose flap will be prepared from the hypothenar eminence. The flap will be based on ulnar artery perforators and will be elevated carefully to preserve its vascular supply. It will then be rotated and placed over the median nerve to provide a soft-tissue cushion that prevents postoperative adhesion and promotes nerve healing. The flap will be fixed in place with absorbable sutures, and the skin will be closed in layers.

Category
Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center
Khatam hospital of shahrood

Full name of responsible person
saeed enayati

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
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
Islamic Azad University
Proportion provided by this source
5
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
Shahroud University of Medical Sciences
Full name of responsible person
saeed enayati
Position
Associate professor
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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

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

In case of a request from the ethics committee, the data will be provided in Excel file format.

When the data will become available and for how long

Starting from January 2026

To whom data/document is available

Ethics Committee, Reviewers, and Supervising Professors

Under which criteria data/document could be used

In case of a request from the ethics committee, the data will be provided in Excel file format.

From where data/document is obtainable

Supervisor and Principal Investigator

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

In the event of an official request for access to study data or documentation, the process is as follows: the request must be submitted in writing by the relevant authority (such as the Ethics Committee or research institutions), clearly stating the purpose. The research team will then review the request, and upon approval, the data will be provided in a structured format (such as Excel or PDF), ensuring confidentiality and adherence to ethical research standards.

Comments