

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparative study of the efficacy of Neurobion and corticosteroid injections under ultrasound guidance in the treatment of carpal tunnel syndrome

Protocol summary

Study aim

comparative study of the efficacy of Neurobion and corticosteroid injections in patients with mild to moderate CTS

Design

This study was a randomized, double-blind, parallel-group, controlled clinical trial conducted on 44 patients. Randomization was performed using the RAND function in Excel.

Settings and conduct

Samples will from Mahdieh Hospital, Modares Hospital, and Modaava Pain Clinic. The total sample size is 44 patients, who will be divided into two groups of 22. Group 1 will receive 1 ml of methylprednisolone and Group 2, Neurobion. Both injections will be administered under ultrasound guidance using in-plane technique with hydrodissection, delivered from the ulnar side.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Individuals aged 20 to 65 years who meet the clinical criteria for carpal tunnel syndrome (CTS), including paresthesia, dysesthesia, pain, and hand weakness that are exacerbated by repetitive use or during sleep and relieved by shaking the hand, with positive Phalen's and Tinel's tests on physical examination, are eligible for inclusion. Diagnosis must be confirmed by electrodiagnostic testing. Exclusion criteria: Pregnancy; underlying metabolic disorders history of corticosteroid injection within the past three months; thenar muscle atrophy; prior CTS surgery; concomitant neuropathy or radiculopathy; and history of malignancy.

Intervention groups

Patients were randomly allocated into two intervention groups: Group 1: Injection into the carpal tunnel using a local corticosteroid. Group 2: Injection into the carpal tunnel using Neurobion. Both injections were performed using the same technique, injection site, needle size, and

injection volume to ensure procedural and visual uniformity between the two groups.

Main outcome variables

Age, Median Nerve Conduction Velocity, Nerve Response Latency, Pain Severity, Hand Symptoms and Function Severity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170311033000N6**
Registration date: **2026-06-03, 1405/03/13**
Registration timing: **registered_while_recruiting**

Last update: **2026-06-03, 1405/03/13**

Update count: **0**

Registration date

2026-06-03, 1405/03/13

Registrant information

Name

Masume Bayat

Name of organization / entity

Shahid beheshti university of medical sciences

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-05-23, 1405/03/02

Expected recruitment end date

2027-03-06, 1405/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the efficacy of Neurobion and corticosteroid injections under ultrasound guidance in the treatment of carpal tunnel syndrome

Public title

study of the efficacy of Neurobion in the treatment of carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

People with a median nerve SNAP peak latency greater than 3.6 People with a median nerve CMAP onset latency greater than or equal to 4.2

Exclusion criteria:

Pregnancy Metabolic disease such as (Diabetes, Thyroid, RA, ...) Corticosteroid injection within the past three months Thenar atrophy CTS surgery Neuropathy or Radiculopathy Malignancy

AgeFrom **20 years** old to **65 years** old**Gender**

Both

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget sample size: **44****Randomization (investigator's opinion)**

Randomized

Randomization description

Patients will be allocated to the two treatment groups using simple randomization with a 1:1 allocation ratio. For this purpose, a numbered list will first be prepared for the 44 participants. Then, using the RAND function in Microsoft Excel, a random number will be generated for each participant. Based on the sorted random numbers, patients will be randomly assigned into two groups of 22 participants receiving either Neurobion or corticosteroid injection. The allocation sequence will be maintained by a person not involved in the outcome assessment process and will be placed in opaque, sequentially numbered sealed envelopes to ensure allocation concealment.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients were unaware of the type of medication administered, as the syringes were prepared by an

independent individual and were identical in appearance and the injection volume was equal in both groups. The data analyst received the data set labeled only as Group A and Group B, and the allocation code was revealed only after completion of the statistical analysis and documentation of the results. Thus, neither the participants nor the data analyst were aware of the type of intervention administered.

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

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Floor 13, Block A, Ministry of Health & Medical Education Headquarters, Between Zarafashan & South Falamak, Qods Town, Tehran, Iran.

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Approval date

2026-02-01, 1404/11/12

Ethics committee reference number

IR.SBMU.MSP.REC.1404.715

Health conditions studied**1****Description of health condition studied**

Carpal tunnel syndrome

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Peak Latency, Onset Latency

Timepoint

before injection

Method of measurement

Electromyography nerve conduction study

2

Description

Pain Score

Timepoint

before injection

Method of measurement

Visual Analogue Scale questionnaire

3

Description

Symptom Severity and Hands Function

Timepoint

before injection

Method of measurement

Boston Carpal Tunnel Questionnaire

4

Description

Amplitude of Sensory Nerve Action Potential and Compound Motor Action Potential

Timepoint

before injection

Method of measurement

Electromyography nerve conduction study

Secondary outcomes

1

Description

Peak Latency, Onset Latency

Timepoint

3 months after injection

Method of measurement

Electromyography nerve conduction study

2

Description

Pain Score

Timepoint

3 months after injection

Method of measurement

Visual Analogue Scale questionnaire

3

Description

Symptom Severity and Hands Function

Timepoint

3 months after injection

Method of measurement

Boston Carpal Tunnel Questionnaire

4

Description

Amplitude of Sensory Nerve Action Potential and Compound Motor Action Potential

Timepoint

3 months after injection

Method of measurement

Electromyography nerve conduction study

Intervention groups

1

Description

Intervention Group 1: Corticosteroid injection (1 mL methylprednisolone 40 mg/mL + 1 mL Lidocaine) plus wrist splint with 5° extension.

Category

Treatment - Drugs

2

Description

Intervention Group 2: Injection of 1.5 mL Octobion + 0.5 mL Lidocaine plus a wrist splint positioned at 5° of extension.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Mahdieh Hospital

Full name of responsible person

Masumeh Bayat

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2

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Vice chancellor for research
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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
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

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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