Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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, ...) Croticosteroid injection within the past three months Thenar atrophy CTS surgery Neuropathy or Radiculopathy Malignancy
Age
From **20 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Data analyser

Sample size
Target 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 pf the type of intervention adminstered.
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
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
Street address
Mahdieh Hospital, Rajab Nia Street, Shishehgar Alley, Fadaian Inslam Street, Shosh Square, Tehran
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2

Recruitment center
Name of recruitment center
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Recruitment center
Name of recruitment center
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Full name of responsible person
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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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5th floor-department No.2-Shahid Aarabi street-Yaman Street-Tehran
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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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Assistant Professor
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Email

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