

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

Phone

+98 21 2273 1112

Email address

bayat.masyme@sbmu.ac.ir

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

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 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

Street address

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

City

Tehran

Province

Tehran

Postal code

1985717443

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

City

Tehran

Province

Tehran

Postal code

1185817311

Phone

+98 21 5506 2628

Email

bayat.masyme@sbmu.ac.ir

2

Recruitment center

Name of recruitment center

Shahid Modarres Hospital

Full name of responsible person

Seyed Ahmad Raeeisolsadat

Street address

Shahid Modarres Hospital, Saadat Abad street, Tehran

City

tehran

Province

Tehran

Postal code

1998734383

Phone
+98 21 2207 4087
Email
a_raeissadat@sbmu.ac.ir

empty
Country of origin
Type of organization providing the funding
Academic

3

Recruitment center

Name of recruitment center
Modava Pain Clinic
Full name of responsible person
Seyed Ahmad Raeisolsadat
Street address
No. 6, Golban street, Tarbiat moalem street ,
Farahzadi Blvd, Shahrak e qarb
City
Tehran
Province
Tehran
Postal code
1998734333
Phone
+98 21 8868 8881
Email
Modavapainclinic@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Vice chancellor for research
Street address
5th floor-department No.2-Shahid Aarabi street-
Yaman Street-Tehran
City
Tehran
Province
Tehran
Postal code
1985717434
Phone
+98 21 2243 9780
Email
info@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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masumeh Bayat
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Mahdieh Hospital, Tehran
City
tehran
Province
Tehran
Postal code
۱۱۸۵۸۱۷۳۱۱
Phone
+98 21 5506 2628
Fax
Email
bayat.masyme@sbmu.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Masume Bayat
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Physical Medicine
Street address
Mahdieh Hospital, Shishegar Alley, Fadaeean Islam
Ave., Shoush square, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
۱۱۸۵۸۱۷۳۱۱
Phone
+98 21 5506 2628
Email
bayat.masyme@sbmu.ac.ir

Person responsible for updating data

bayat.masyme@sbmu.ac.ir

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masume Bayat

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Mahdiah Hospital, Shishegar Alley, Fadaeean Islam Ave., Shoush square, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

11185A1V311

Phone

+98 21 5506 2628

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