

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of the effect of hydrodissection combined with corticosteroids and open surgery in the treatment of moderate and severe carpal tunnel syndrome: A controlled clinical trial

Protocol summary

Study aim

Comparison of the effectiveness of hydrodissection combined with corticosteroids and open surgery in the treatment of moderate and severe carpal tunnel syndrome.

Design

Clinical trial, with two parallel groups, non-randomized, without blinding, on 40 patients

Settings and conduct

Patients with moderate to severe carpal tunnel syndrome who refer to physical medicine and rehabilitation or orthopedic clinics under the supervision of Isfahan University of Medical Sciences will be allocated to the surgery group if they wish to undergo surgery, and to the hydrodissection group if they do not agree to surgery or want to delay it for at least 6 months. In this study, only the data analyst is unaware of the patient grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Moderate to severe carpal tunnel syndrome, age over 18, no injection treatment or physiotherapy and modality within the last three months. Exclusion criteria: Radiculopathy, plexopathy, peripheral neuropathy, uncontrolled systemic diseases.

Intervention groups

The first group received median nerve release through hydrodissection, utilizing 5 cc of 5% dextrose solution and 1 cc of triamcinolone, guided by ultrasound in a single session. Meanwhile, the second group was treated surgically with a longitudinal incision on the distal forearm along the fourth finger.

Main outcome variables

Visual analogue scale score, Boston carpal tunnel questionnaire score for pain and function, amplitude and latency of median nerve sensory and motor responses

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180507039571N5**

Registration date: **2025-03-26, 1404/01/06**

Registration timing: **prospective**

Last update: **2025-03-26, 1404/01/06**

Update count: **0**

Registration date

2025-03-26, 1404/01/06

Registrant information

Name

Shervin Ghaffari hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3611 5208

Email address

shghaffari@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-22, 1404/03/01

Expected recruitment end date

2026-01-20, 1404/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of hydrodissection combined with corticosteroids and open surgery in the treatment of moderate and severe carpal tunnel syndrome: A controlled clinical trial

Public title

Comparison of the effect of hydrodissection combined with corticosteroids and open surgery in the treatment of moderate and severe carpal tunnel syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with moderate to severe Carpal tunnel syndrome based on electrodiagnostic testing Age above 18 Male and female gender Not receiving carpal tunnel injection treatment and physiotherapy and modalities in the last three months

Exclusion criteria:

Radiculopathy Plexopathy Motor neuron disease Peripheral neuropathy pregnancy Hand and bone joint deformity History of hand trauma Having uncontrolled systemic diseases, such as inflammatory joint diseases and uncontrolled diabetes Suffering from thenar atrophy and severe weakness of the palm muscles

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of school of medicine, Isfahan University of Medical Sciences

Street address

Vice President for Research and Technology, Building

No. 4, Isfahan University of Medical Sciences, Hezar Jerib Street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Approval date

2025-03-10, 1403/12/20

Ethics committee reference number

IR.MUI.MED.REC.1403.506

Health conditions studied

1

Description of health condition studied

Carpal tunnel syndrome

ICD-10 code

G56.0

ICD-10 code description

Carpal tunnel syndrome

Primary outcomes

1

Description

Wrist pain score in carpal tunnel syndrome patients

Timepoint

Before the intervention and one, three, and six months after the completion of the intervention

Method of measurement

Using a visual analogue scale

2

Description

Severity of dysfunction

Timepoint

Before the intervention and one, three, and six months after the completion of the intervention

Method of measurement

Using the Boston carpal tunnel questionnaire (BCTQ)

3

Description

Sensory and motor wave amplitude of the median nerve

Timepoint

Before and three months after the intervention

Method of measurement

Electrodiagnostic study

4

Description

Median nerve sensory and motor wave latency

Timepoint

Before and three months after the intervention

Method of measurement

Electrodiagnostic study

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Using an ultrasound device (ALPINION E-CUBE9 with 3-12 Mhz linear probe.ALPINION medical system.Seoul.South Korea), a hydrodissection injection of 5 cc of 5% dextrose water and 1 cc of triamcinolone is administered without local anesthesia using an inplane approach from the ulnar side to release the median nerve from the surrounding tissue.

Category

Treatment - Drugs

2

Description

Intervention group 2: Median nerve release surgery is performed with a 2.5 cm long incision 1.5 cm distal to the forearm along the fourth finger.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Shervin Ghaffari Hoseini

Street address

Amin hospital, Sonbolestan Alley, Ibn Sina Avenue, Shohada Square, Isfahan

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Email

shghaffari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholam Reza Askari

Street address

3rd floor, Vice President for Research and Technology of the University, 4th building, Isfahan University of Medical Sciences, Hezar Jarib Avenue, Isfahan

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intres@nui.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Esfahan 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

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shervin Ghaffari Hoseini

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Physical Medicine

Street address

Isfahan Cardiovascular Research Institute, Shahid Rahmani Alley, next to Shahid Chamran Heart Hospital, after Shahrestan Bridge, 3rd Mushtaq St.

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Shervin Ghaffari Hoseini

Position

Assistant professor

Latest degree

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Person responsible for updating data

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