Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Isfahan

Province
Isfehan

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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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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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

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Position
Assistant professor

Latest degree
Specialist

Other areas of specialty/work
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Person responsible for updating data

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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