Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Ultrasound-Guided Median nerve Hydrodissection with Corticosteroid Injection in the treatment of mild to moderate Carpal Tunnel Syndrome

Protocol summary

Study aim

This study aims to examine the effect of median nerve hydrodissection and to acquire data on the added value of corticosteroid injection when using hydrodissection as a treatment for patients with carpal tunnel syndrome.

Design

prospective, block randomized allocation clinical trial with 2 arm parallel and control groups, double masked (Participant, Outcomes Assessor)

Settings and conduct

The study population are patients with clinical and electrophysiological symptoms of mild to moderate CTS who referred to the physical medicine and rehabilitation clinics of Imam Khomeini and Sina hospitals. After examining the inclusion and exclusion criteria, 60 patients are randomly assigned to one of three study groups. Each patient is evaluated initially (before injection) and at intervals of two weeks, 1, 3 and 6 months after injection. Assessments will include visual analog (VAS), Boston Carpal Tunnel Questionnaire, Electrodiagnostic test data, dynamometer, and median nerve cross-section (CSA) measurements by ultrasound.

Participants/Inclusion and exclusion criteria

Adult men or women aged 18 - 80 years with clinical and electromyographic diagnosis of Carpal Tunnel Syndrome any accompanying orthopedic or neurologic disorders that could mimic CTS.

Intervention groups

Group A: Corticosteroid Hydrodissection Injection Ultrasound-guided hydrodissection using 1ml of 40mg triamcinolone acetonide mixed with 1ml of 2% lidocaine hydrochloride and 3cc Normal Saline. Group B: Hydrodissection Injection without Corticosteroid Ultrasound-guided hydrodissection using 1ml of 2% lidocaine mixed with 4cc Normal Saline. Group C: control group Ultrasound in-plane ulnar approach injection using 1 mL of triamcinolone is as per current treatment practices.

Main outcome variables

Change from baseline of severity of symptoms and functional status after Hydrodissection injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210613051566N1**
Registration date: **2021-12-17, 1400/09/26**
Registration timing: **prospective**

Last update: **2021-12-17, 1400/09/26**
Update count: **0**

Registration date

2021-12-17, 1400/09/26

Registrant information

Name

sahar ghorbanpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8870 1551

Email address

sahar.ghorbanpour@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Ultrasound-Guided Median nerve Hydrodissection with Corticosteroid Injection in the treatment of mild to moderate Carpal Tunnel Syndrome

Public title

Comparison of Ultrasound-Guided Median nerve Hydrodissection with Corticosteroid Injection in the treatment of mild to moderate Carpal Tunnel Syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmed clinical and Electrophysiological diagnosis of Carpal Tunnel Syndrome with mild to moderate degree

Exclusion criteria:

Confirmed clinical and Electrophysiological diagnosis of CTS with severe degree Patients with suspicious of CTS mimic condition, including cervical radiculopathy, polyneuropathy, brachial plexopathy, thoracic outlet syndrome Recent corticosteroid injection to the carpal tunnel within 6 months Previous history of carpal tunnel surgical release Steroid injection contraindications Pregnancy Cancer Coagulopathy

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **60**

More than 1 sample in each individual

Number of samples in each individual: **2**

In some patients both hands are involved

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization with help of www.sealedenvelope.com website. According to treatment groups, block sizes and list length, the website generates a list of random codes consisting of an English letter and digits. These codes are printing the codes on a card, and placing the cards in a sealed envelope (SNOSE method). After generating the list, each code will be printed on one card that, after shuffling, are placed in envelopes. Each patient will be given an envelope to assign to one of the groups. Also, in a separate list, the person is assigned to the code taken out of the envelope.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study participants and outcomes assessor are masked.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences, Sina hospital

Street address

Room 605، Secretariat of the Ethics Committee in University Biomedical Research، Vice Chancellor for Research and Technology, 6th Floor, Central University Organization, Corner of Ghods St., Keshavarz Blvd.

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2021-02-28, 1399/12/10

Ethics committee reference number

IR.TUMS.SINAHOSPITAL.REC.1399.121

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

Boston carpal tunnel syndrome questionnaire (BCTQ)

Timepoint

Pre-treatment, 1st, 3rd and 6th months after injection

Method of measurement

five-point rating scale questionnaire

Secondary outcomes

1

Description
Visual Analog Scale (VAS) for Pain
Timepoint
Pre injection, 2 weeks, 1, 3 and 6 months intervals
Method of measurement
Visual and numeric scale

2

Description
Cross-sectional area of the Median nerve
Timepoint
Pre injection, 1, 3 and 6 months intervals
Method of measurement
Ultrasound device

3

Description
Conduction Velocity, Distal Latency and Amplitude of Median nerve SNAP & CMAP
Timepoint
Pre injection, 1, 3 and 6 months intervals
Method of measurement
EMG- NCV

4

Description
Hand grip strength
Timepoint
Pre injection, 1, 3 and 6 months intervals
Method of measurement
Dynamometer

Intervention groups

1

Description
Intervention group: Patients in this group will undergo a Ultrasound-guided Median nerve hydrodissection with corticosteroid injection. Total of 5cc solution consisting of 1cc of Triamcinolone acetonide (40mg), 1cc of lidocaine, and 3cc of saline is used. Using ultrasound guidance and aseptic technique, the needle will be inserted from an ulnar approach, then be angled deep to inject 2 ml of mixture for separating nerve from Flexor tendons beneath. The needle will then be angled superficial to the median nerve and 3ml of mixture will be injected to to peel the median nerve off the overlying flexor retinaculum.
Category
Treatment - Other

2

Description
Intervention group: Patients in this group will undergo a Ultrasound-guided Median nerve hydrodissection without corticosteroid injection. Total of 5cc solution consisting of 1cc of lidocaine, and 4cc of saline is used. Using ultrasound guidance and aseptic technique, the needle will be inserted from an ulnar approach, then be angled deep to inject 2 ml of mixture for separating nerve from Flexor tendons beneath. The needle will then be angled superficial to the median nerve and 3ml of mixture will be injected to to peel the median nerve off the overlying flexor retinaculum.
Category
Treatment - Other

3

Description
Control group: Patients in this group will undergo a routine and standard Corticosteroid injection for CTS treatment. Using ultrasound guidance and aseptic technique, the needle will be inserted from an ulnar approach, and 1ml of Triamcinolone acetonide (40mg) will be injected into the area above Median nerve without separating the nerve from surrounding structures.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam khomeini hospital
Full name of responsible person
Sahar Ghorbanpour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
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Keshavarz Blvd, Qods street, TUMS
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Postal code

1416753955
Phone
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Email
drazadvari@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Sahar Ghorbanpour
Position
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Person responsible for updating data

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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The data of the study participants will be evaluated for statistical analysis, and their results will be published in

the form of an article.

When the data will become available and for how long

Immediately after the publication of the results in the form of a scientific article, the results of data analysis will be available to researchers at the request of the data.

To whom data/document is available

Researchers of this project and individuals who have the right to access the project data based on the written permission of the corresponding researcher can access the project data.

Under which criteria data/document could be used

If the permission of the main researcher of the project is obtained with an acceptable justification and explanation, the data obtained from this project can be used.

From where data/document is obtainable

Imam Khomeini Hospital Complex, Physical Medicine and Rehabilitation department, Dr Mohadese Azadvari

What processes are involved for a request to access data/document

A written request will be sent to the researcher in charge of the study with appropriate evidence and justification; Once approved by him, access to data and documents will be possible.

Comments