

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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 acetate 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](http://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.

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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 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 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

#### **Street address**

Keshavarz blvd

#### **City**

Tehran

#### **Province**

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#### **Postal code**

1419733141

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#### **Email**

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## **Sponsors / Funding sources**

## 1

### **Sponsor**

#### **Name of organization / entity**

Tehran University of Medical Sciences

#### **Full name of responsible person**

Mohadese Azadvari

#### **Street address**

Keshavarz Blvd, Qods street, TUMS

#### **City**

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#### **Province**

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#### **Postal code**

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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**

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**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

assistant professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

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**Email**

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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**