

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of ultrasound-guided injection of Dextrose 5% in Water (D5W) and Corticostroid in patients with carpal tunnel syndrome

#### Protocol summary

##### Study aim

Comparison of the effectiveness of 5% dextrose and methylprednisolone injection in improving pain and function in patients with Carpal tunnel syndrome.

##### Design

A clinical trial in phase 2-3, with 2 parallel groups, double-blind, randomized trial with the block randomization method (with same block length), On 42 patients.

##### Settings and conduct

The intervention will be performed on patients with mild or moderate carpal tunnel syndrome in Imam Reza clinic in Shiraz. After filling out the informed consent form and Boston questionnaire and visual analogue scale, determining latency and amplitude of Median nerve CMAP and SNAP, and determining the cross-sectional area of the Median nerve, one of 5% dextrose or methylprednisolone will be injected for patients. In 1 and 3 months later follow up, all parameters will be measured again. Patients, the data collector, and the data analyst will be blind. These individuals are unaware of the type of medication that used.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 30 to 65 years; Mild or moderate Carpal tunnel syndrome according to electrodiagnostic criteria Exclusion criteria: History of polyneuropathy, brachial plexopathy, thoracic outlet syndrome, active radiculopathy, or rheumatological diseases; Pregnancy; Neoplasm in involved wrist

##### Intervention groups

Dextrose group: injection of 2cc 5% dextrose (Shiraz Serum Pharmaceutical Company) into carpal tunnel. Steroid group: injection of 1cc (40mg) methylprednisolone acetate ( Exir Pharmaceutical Company) with 1cc normal saline (Darou Pakhsh factory).

##### Main outcome variables

Median nerve (MN) Compound Muscle Action Potential

(CMAP) latency; MN CMAP amplitude; MN Sensory Nerve Action Potential (SNAP) latency; MN SNAP amplitude; MN sonographic cross-sectional area; Visual Analogue Scale score; Severity score in Boston Carpal tunnel Syndrome Questionnaire (BCTQ); Functional BCTQ score.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200705048007N1**

Registration date: **2021-03-23, 1400/01/03**

Registration timing: **prospective**

Last update: **2021-03-23, 1400/01/03**

Update count: **0**

##### Registration date

2021-03-23, 1400/01/03

##### Registrant information

##### Name

Farzaneh Rezaei motlagh

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 71 3235 1087

##### Email address

farzaneh.rm7@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-04-21, 1400/02/01

##### Expected recruitment end date

2021-08-22, 1400/05/31

**Actual recruitment start date**

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

Comparison of the effectiveness of ultrasound-guided injection of Dextrose 5% in Water (D5W) and Corticostroid in patients with carpal tunnel syndrome

**Public title**

Effect of Dextrose 5% in Water (D5W) injection in carpal tunnel syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Completing and signing the conscious consent form Age between 30 and 65 years Mild to moderate Carpal tunnel syndrome , based on electrodiagnostic criteria Paresthesia or dysesthesia or pain in the hand and wrist (which is associated with a particular condition, excessive use of the hand or the occurrence at night or relieved by shaking the hand) Existence of one of the following in the physical examination: positive Phalen test, positive Tinel test, weakness in the thenar muscles, sensory defects in the sensory area of the Median nerve in the hand It has been at least 3 months since the onset of symptoms and has not responded to non-invasive treatments

**Exclusion criteria:**

Positive history of polyneuropathy Positive history of surgery on involved wrist History of previous steroid injections into the affected wrist over the past year History of rheumatological diseases such as rheumatoid arthritis Pregnancy Neoplasm in involved wrist History of allergy to steroids Infection at the injection site Coagulopathies and bleeding tendency Positive history of brachial plexopathy Positive history of thoracic outlet syndrome Positive history of active radiculopathy

**Age**

From **30 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **42**

More than 1 sample in each individual

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

In cases which the participant has (moderate or mild) carpal tunnel syndrome in both wrists, each wrist is considered and treated as a separate sample.

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

In this study, block randomization method is used. Blocking is usually used to balance the number of samples assigned to each of the study groups. The size of all blocks is equal and, in this study, we will have blocks length of 4, including 2 patients in the dextrose group and 2 patients in the methyl group. Randomization is done by computer using Random allocation software version 1.0.0. For concealment, we use random allocation concealment using opaque sealed and sequentially numbered envelopes, so that the assigned group is not known before the individual is assigned. In this method, each of the random sequences created is recorded on a card and the cards are placed in the envelopes in order. In order to maintain the random sequence, the envelopes are numbered in the same way on the outer surface. Finally, the envelopes are glued and placed in a box, respectively. Based on the order of entry of eligible patients into the study, one of the envelopes is opened in order and their assigned group is revealed.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

At the time of patients enrollment and taking informed consent, they are told that they will be injected with one of the drugs methylprednisolone or 5% dextrose. For injection, covered syringes with same shape and size whose contents are not visible are used, and thus patients do not know the exact type of medication to be injected. The physician who performs injections knows the type of medication based on the patient`s code. A person who fills out severity and function questionnaires, as well as a person who measures the criteria for electrodiagnosis and ultrasound during follow up sessions, are not aware of the type of medication for each person, Because just the name and code of each person will be written on the data collection forms and the type of intervention will not be mentioned. The statistical consultant who will analyze the final data does not know what drug has been injected for each group and the groups data will be given to him under the pseudonyms A and B.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

**Street address**

Shiraz University of Medical Sciences, Karimkhan  
Zand Boulevard

**City**

Shiraz

**Province**

Fars

**Postal code**

7134814336

**Approval date**

2019-08-17, 1398/05/26

**Ethics committee reference number**

IR.SUMS.MED.REC.1398.348

## 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**

cross sectional area of median nerve

**Timepoint**

At the beginning of the study (before the intervention) , 1  
and 3 months after the intervention (injection)

**Method of measurement**

manual by sonography

### 2

**Description**

Median sensory nerve action potentials amplitude

**Timepoint**

At the beginning of the study (before the intervention) , 1  
and 3 months after the intervention (injection)

**Method of measurement**

electromyography

### 3

**Description**

Median sensory nerve action potentials latency

**Timepoint**

At the beginning of the study (before the intervention) , 1  
and 3 months after the intervention (injection)

**Method of measurement**

electromyography

### 4

**Description**

Median compound motor action potentials latency

**Timepoint**

At the beginning of the study (before the intervention) , 1

and 3 months after the intervention (injection)

**Method of measurement**

electromyography

### 5

**Description**

Median compound muscle action potentials amplitude

**Timepoint**

At the beginning of the study (before the intervention) , 1  
and 3 months after the intervention (injection)

**Method of measurement**

electromyography

### 6

**Description**

pain score by visual analogue scale

**Timepoint**

At the beginning of the study (before the intervention) , 1  
and 3 months after the intervention (injection)

**Method of measurement**

visual analogue scale

### 7

**Description**

severity score by Boston carpal tunnel syndrome  
questionnaire

**Timepoint**

At the beginning of the study (before the intervention) , 1  
and 3 months after the intervention (injection)

**Method of measurement**

Boston carpal tunnel syndrome questionnaire

### 8

**Description**

Functional score by Boston carpal tunnel syndrome  
questionnaire

**Timepoint**

At the beginning of the study (before the intervention) , 1  
and 3 months

**Method of measurement**

Boston carpal tunnel syndrome questionnaire

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Only once, under ultrasound  
guidance, 2 cc 5% dextrose product of Shiraz Serum  
Pharmaceutical Company is injected through a needle  
gauge 23 into the carpal tunnel area (into the scaphoid  
and pisiform bones plate).

**Category**

Treatment - Other

## 2

### Description

Intervention group: Only once, under ultrasound guidance, 40 mg(1 cc) methylprednisolone acetate product of Exir Pharmaceutical Company with 1 cc normal saline product of Darou Pakhsh Factory is injected through a needle gauge 23 into the carpal tunnel area (into the scaphoid and pisiform bones plate).

### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Emam Reza clinic

##### Full name of responsible person

Aref Nasiri

##### Street address

Emam Reza Clinic, next to the Namazi hospital, Namazi square

##### City

Shiraz

##### Province

Fars

##### Postal code

7134814734

##### Phone

+98 71 3212 7000

##### Email

nasiri.rf@gmail.com

##### Web page address

<https://emamreza.sums.ac.ir/>

### 2

#### Recruitment center

##### Name of recruitment center

Faghihi hospital

##### Full name of responsible person

Farzaneh Rezaei motlagh

##### Street address

Faghihi hospital, next to the medical school, Karimkhan Zand Boulevard

##### City

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##### Province

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7134844119

##### Phone

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##### Email

faghihihsp@sums.ac.ir

##### Web page address

<https://faghihi.sums.ac.ir/>

### 3

#### Recruitment center

##### Name of recruitment center

Rajaei Hospital

##### Full name of responsible person

Farzaneh Rezaei motlagh

##### Street address

Rajaei hospital, Chamran boulevard

##### City

Shiraz

##### Province

Fars

##### Postal code

7194815711

##### Phone

+98 71 3636 4001

##### Email

rajaeehospital@sums.ac.ir

##### Web page address

<https://rajaeehosp.sums.ac.ir/>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Abbas Rezaeian zadeh

##### Street address

Shiraz University of Medical Science, Karimkhan zand boulevard

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##### Web page address

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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

Shiraz 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**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh Rezaei motlagh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

No.11, Hamoon2 building, 4.8 Alley, Shahid Abaeian Ave., Neshat Street

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Medical doctor

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh Rezaei motlagh

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

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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**

Yes - There is a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

**Title and more details about the data/document**

Demographic information file, all potential data after unidentifiable individuals, including main outcome.

**When the data will become available and for how long**

Access period starts 6 months after publishing the results.

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Use of data and documents in parts of articles such as: Review of the background of the subject, Analysis and conclusion and also in Review and meta-analysis studies is allowed.

**From where data/document is obtainable**

Correspondence with the main researcher, Farzaneh Rezaei Motlagh with e-mail address: farzaneh.rm7@gmail.com

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

Sending an e-mail requesting the receipt of documents, along with providing evidence of the academic position of the person related to the research topic, stating the purpose of the request for documentation. This e-mail will be answered within a maximum of one month.

## Comments