

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effectiveness of ultrasound-guided local corticosteroid injection with dextrose 5% solution injection in carpal tunnel syndrome.

#### Protocol summary

##### Study aim

Comparison of the effectiveness of local corticosteroid injection with injection of dextrose 5% solution in patients with carpal tunnel syndrome.

##### Design

Double blinded randomized control trial.

##### Settings and conduct

This study will be conducted on physical medicine and rehabilitation department of Rasool Akram hospital, Tehran, Iran. Patients with mild to moderate carpal tunnel syndrome (based on electrodiagnostic study) will be included in the study. Patients will be categorized into one of the following groups, using block randomization method: A Group: Will receive ultrasound-guided injection of 1CC triamcinolone into carpal tunnel. B Group: Will receive ultrasound-guided injection of 5 CC dextrose 5% into carpal tunnel. Patients in the both groups will receive the conservative treatments for carpal tunnel syndrome including wrist splints for six weeks as well. Patients will be followed after 2 weeks, one month and 6 months after injections. The pain intensity (Visual analogue scale) and the electrodiagnostic parameters are the main outcomes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Clinical diagnosis of carpal tunnel syndrome based on history (paresthesia over the distribution of median nerve) and positive Tinel and Phalen's tests. 2- Mild to moderate severity based on electrodiagnostic study. 3- Age between 18-65 years. exclusion criteria: Severe CTS, thenar atrophy, contraindication for injection, previous treatment, Neoplasm or trauma, tenderness and fracture of wrist, cervical radiculopathy, polyneuropathy.

##### Intervention groups

A Group: Ultrasound-guided injection of 1CC triamcinolone into carpal tunnel. B Group: Ultrasound-guided injection of 5 CC dextrose 5% into carpal tunnel.

##### Main outcome variables

Pain intensity (Visual analogue scale) and the

electrodiagnostic parameters.

#### General information

##### Reason for update

A few days before 2019-12-10, I had requested for expected recruitment date to be on 2019-12-10. but unfortunately my request was accepted two days later and now the chief editor wants to know if I started my clinical trial 2 days sooner! but I didn't. I started it exactly on 2019-12-12 after getting confirmation. the reason was busy schedule of the person who confirmed the registration on 12th. I forgot to write down the achieved date of starting my clinical trial and now I want to update that. thanks

##### Acronym

CTS

##### IRCT registration information

IRCT registration number: **IRCT20180603039969N1**  
Registration date: **2019-12-12, 1398/09/21**  
Registration timing: **registered\_while\_recruiting**

Last update: **2020-07-13, 1399/04/23**

Update count: **1**

##### Registration date

2019-12-12, 1398/09/21

##### Registrant information

###### Name

Sara Moradnia

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 61 3553 1210

###### Email address

moradnia.s@ajums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

**Expected recruitment start date**

2019-12-10, 1398/09/19

**Expected recruitment end date**

2020-01-09, 1398/10/19

**Actual recruitment start date**

2019-12-12, 1398/09/21

**Actual recruitment end date**

2019-12-18, 1398/09/27

**Trial completion date**

2020-06-18, 1399/03/29

**Scientific title**

Comparison of the effectiveness of ultrasound-guided local corticosteroid injection with dextrose 5% solution injection in carpal tunnel syndrome.

**Public title**

Comparison of effectiveness of corticosteroid with dextrose in treatment of carpal tunnel syndrome.

**Purpose**

Treatment

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

Patients with clinical diagnosis of carpal tunnel syndrome (paresthesia over the median nerve territory in the hand). Mild to moderate severity of carpal tunnel syndrome, based on electrodiagnostic studies. Age between 18-65 years,

**Exclusion criteria:**

Severe CTS ( based on electrodiagnostic data). Signs of thenar atrophy. Contraindication for injection ( such as history of hypersensitivity to corticosteroid, signs of local infection, immune deficiency, needle phobia. Diseases that mimic symptoms of carpal tunnel syndrome such as polyneuropathy, radiculopathy, and thoracic outlet syndrome. Surgical treatment or local injection in the last six months. Neoplastic or traumatic origin. Tenderness and fracture of wrist bones.

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Investigator

**Sample size**

Target sample size: **54**

Actual sample size reached: **54**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients will be categorized into one of the following groups, using block randomization method: Group A) Will receive ultrasound-guided injection of 1 ml triamcinolone (40 mg) into the carpal tunnel. Group B) Will receive ultrasound-guided injection of 5 ml dextrose 5% into the carpal tunnel.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patient and the investigator are kept blinded. The injecting syringe is covered with sterile gas. Therefore, the investigator will be kept blinded to the type of injecting solution. Furthermore, the patient will be kept blinded to the type of injecting solution.

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Iran University of Medical Sciences.

**Street address**

Ethics committee, medical school, Iran University of Medical Sciences, Hemmat highway, Tehran, Iran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2018-11-20, 1397/08/29

**Ethics committee reference number**

IR.IUMS.FMD.REC.1397.216

**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**

Pain intensity (Visual analogue scale)

**Timepoint**

Baseline, and after 2 weeks, one month and 6 months after injection.

**Method of measurement**

10 point VAS scale.

## 2

### Description

Electrodiagnosis parameters

### Timepoint

Baseline, and after 2 weeks, one month and 6 months after injection.

### Method of measurement

Electrodiagnostic study machine

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

One session of ultrasound-guided 1 CC Triamcinolone (Exir co, Tehran, Iran) injection into the carpal tunnel.

#### Category

Treatment - Drugs

### 2

#### Description

One session of ultrasound-guided 5 CC dextrose 5% solution (Ghazi co, Tehran, Iran) injection into the carpal tunnel.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Rasoul-akram hospital

##### Full name of responsible person

Dr. Arash Babaei-Ghazani

##### Street address

Physical medicine department- Rasoul-akram hospital- Niayesh street- Satarkhan Ave- Tehran, Iran.

##### City

Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 6435 2683

##### Email

arashbabaie@gmail.com

##### Web page address

[http://hrmc.iums.ac.ir/form\\_contact.php?sid=44&slc\\_lang=fa](http://hrmc.iums.ac.ir/form_contact.php?sid=44&slc_lang=fa)

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Dr. seyed Abbas Motevalian

##### Street address

Iran university of medical sciences, hemmat autobahn

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Tehran

##### Province

Tehran

##### Postal code

1445613131

##### Phone

+98 21 8670 2503

##### Email

amotevalian@iums.ac.ir

##### Web page address

<http://vcr.iums.ac.ir/page/3340/%D9%85%D8%B9%D8%A7%D9%88%D9%86%D8%AA-%D8%AA%D8%AD%D9%82%DB%8C%D9%82%D8%A7%D8%AA-%D9%88-%D9%81%D9%86%D8%A7%D9%88%D8%B1%DB%8C>

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Iran University of Medical Sciences

#### Proportion provided by this source

80

#### 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

Persons

## Person responsible for general inquiries

#### Contact

##### Name of organization / entity

Iran University of Medical Sciences

##### Full name of responsible person

Sara moradnia

##### Position

Resident

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Physical Medicine

##### Street address

Physical medicine, Rasoul-akram hospital, Niayesh street, Satarkhan Ave, Tehran, Iran.

##### City

Tehran

**Province**

Tehran

**Postal code**

1445613131

**Phone**

+98 21 6435 2683

**Email**

moradnia.s@ajums.ac.ir

**Web page address**

<http://hrmc.iums.ac.ir/>

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Sara Moradnia

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Physical Medicine

**Street address**

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## Person responsible for updating data

**Contact****Name of organization / entity**

Iran University of Medical Sciences

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Sara Moradnia

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Resident

**Latest degree**

Medical doctor

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Physical Medicine

**Street address**

Physical medicine department, Rasoul-akram hospital, Niayesh street, Satarkhan Ave, Tehran, Iran.

**City**

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**Email**

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**Web page 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**

All collected data can be shared after making patients anonymous.

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

Starting 6 months after publication.

**To whom data/document is available**

Data will be available for researchers on the internet.

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

Data will be shared based on the request of the researchers.

**From where data/document is obtainable**

Dr. Babaei, Physical medicine department, Rasoul-akram hospital, Satarkhan Street, Tehran, Iran.

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

Data will be sent via Email.

**Comments**