

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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

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

City

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

Rasoul akram hospital, Niayesh street, Satarkhan Ave

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 updating data**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 department, 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/

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