

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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)

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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

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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

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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

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Fars

Postal code

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Phone

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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

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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

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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

Farzaneh Rezaei motlagh

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

Resident

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Other areas of specialty/work

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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