Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 Boulvard

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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Fars
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7134814734
Phone
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2

Recruitment center
Name of recruitment center
Faghihi hospital
Full name of responsible person
Farzaneh Rezaei motlagh
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Faghihi hospital, next to the medical scool, Karimkhan Zand Boulevard
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Postal code
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Web page address
https://faghihi.sums.ac.ir/

3

Recruitment center
Name of recruitment center
Rajaee Hospital
Full name of responsible person
Farzaneh Rezaei motlagh
Street address
Rajaee hospital, Chamran boulvard
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Shiraz
Province
Fars
Postal code
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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 boulvard
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Shiraz
Province
Fars
Postal code
7134814336
Phone
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Email
info@sums.ac.ir
Web page address
https://www.sums.ac.ir
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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Person responsible for scientific inquiries

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Position
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Latest degree
Medical doctor

Other areas of specialty/work
Physical Medicine

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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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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