

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of neurofascial dextrose prolotherapy on pain and function of patients with carpal tunnel syndrome

Protocol summary

Study aim

Comparison of efficacy between two groups of dextrose injection of Prolotherapy and Methylprednisolone in CTS patients

Design

After giving the necessary explanations, a signed written consent is obtained from the mentioned patients, and then they are treated with Prolotherapy or Methyl prednisolone by block randomization method.

Settings and conduct

This randomized clinical trial will be performed in Imam Reza Hospital in Tehran in 1400

Participants/Inclusion and exclusion criteria

Inclusion criteria included age 20 to 80 years, patient informed consent and willingness to participate in the study, EMG NCV findings indicate mild to moderate CTS and They have symptom lasted more than three months and the diagnosis has been confirmed by electrodiagnostic examiners.

Intervention groups

Patients were randomly selected (one in between) in one of two groups treated with perinural D5W injection Or methylprednisolone topically. In the first group, under one injection with 5 cc D5W and In the second group, they are injected with 1 cc of methylprednisolone and 0.5 cc of lidocaine in the carpal tunnel area. After injection, they are treated with COCK UP splint.

Main outcome variables

Evaluation of patient performance with Boston questionnaire: Intensity of pain : Electrodiagnostic criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180416039323N3**

Registration date: **2021-11-27, 1400/09/06**

Registration timing: **prospective**

Last update: **2021-11-27, 1400/09/06**

Update count: **0**

Registration date

2021-11-27, 1400/09/06

Registrant information

Name

Zahra Rezasoltani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4382 3476

Email address

z.rezasoltani@ajaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-16, 1400/09/25

Expected recruitment end date

2022-04-21, 1401/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of neurofascial dextrose prolotherapy on pain and function of patients with carpal tunnel syndrome

Public title

The effect of dextrose and corticosteroid injections in CTS patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Nocturnal paresthesia / dysplasia with or without excessive pain on the hands Numbness In the sensory distribution of the median nerve Weakness with atrophic changes in the Median nerve innervated Positive Phalen or Tinel test Age 20 to 80 years They have mild to moderate CTS and their symptoms last for more than three months And have been resistant to drug therapy and splints conscious patient satisfaction

Exclusion criteria:
History of polyneuropathy History of inflammatory arthritis Current use of warfarin Previous steroid injection for CTS Trauma at the injection site Allergy to corticosteroid skin infection at the injection site neoplasm at the injection site History of Brachial plexiopathy History of thoracic outlet syndrome History of wrist surgery History of hypothyroidism History of pregnancy History of rheumatic disorders History of having a pacemaker

Age
From **20 years** old to **80 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are randomly assigned to Prolotherapy or Corticosteroid by block randomization in one of two groups. To randomly assign two groups with 22 participants in each group (44 patients in total), we use block randomization with different block sizes. The size of the blocks is a multiple of 2 and a divisor of 44 (2,4,8). Initially, the size of the blocks is randomly selected. Then for each block, different permutations are determined for the size of the equal group. Finally, one of the permutations is randomly selected. Random numbers are generated using a computer in an independent statistical unit.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committees of AJA University of Medical Sciences

Street address
Imam Reza hospital, Etemad zade street, Fatemi street, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1411718546

Approval date
2021-09-08, 1400/06/17

Ethics committee reference number
IR.AJAUIMS.REC.1400.137

Health conditions studied

1

Description of health condition studied
carpal tunnel syndrom

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Intensity of pain

Timepoint
before intervention, 1 month after intervention, 3 months after intervention

Method of measurement
A 10-point VAS scale that the patient should give a score from 0 to 10

2

Description
Evaluation of patient performance with Boston questionnaire

Timepoint
before intervention, 1 month after intervention, 3 months after intervention

Method of measurement
Boston Questionnaire Score

3

Description
Electrodiagnostic criteria

Timepoint
before intervention, 1 month after intervention, 3 months after intervention

Method of measurement
Based on the latency duration and amp intensity in SNAP, CMAP median nerve, we determine the severity of

involvement and recovery.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 Under one injection with 5 cc D5W inside the carpal tunnel of the wrist

Category

Treatment - Drugs

2

Description

Intervention group 2 Injected with 1 cc of methylprednisolone and 0.5 cc of lidocaine inside the carpal tunnel of the wrist

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital in Tehran

Full name of responsible person

Fahimeh Tafti

Street address

Imam Reza hospital, Etemad zade street, Fatemi street

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fahimeh_tafti65@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Artesh University of Medical Sciences

Full name of responsible person

Mostafa Shahrezaee

Street address

Medical University for the Islamic Republic of Iran's Army, Etemadzadeh Avenue, West Fatemi St., Tehran, Iran

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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

Artesh 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

Artesh University of Medical Sciences

Full name of responsible person

Fahimeh Tafti

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Physical Medicine

Street address

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Person responsible for scientific inquiries

Contact

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Position

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available