

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

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

#### Protocol summary

Registration timing: **prospective**

#### Study aim

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

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

Update count: **0**

#### Registration date

2021-11-27, 1400/09/06

#### 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.

#### 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

#### Settings and conduct

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

#### Recruitment status

**Recruitment complete**

#### Funding source

#### 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.

#### 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

#### 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.

#### Scientific title

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

#### Main outcome variables

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

#### Public title

The effect of dextrose and corticosteroid injections in CTS patients

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180416039323N3**

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

##### 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.AJAUMS.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

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718546

##### Phone

+98 21 8609 6350

##### Email

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

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718541

##### Phone

+98 21 8609 6350

##### Email

fahimeh\_tafti65@yahoo.com

#### 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

Imam Reza hospital, Etemad zade street, Fatemi street

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##### Province

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

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resident

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Artesh University of Medical Sciences

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Fahimeh tafti

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resident

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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