

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

**A comparison between leech therapy and medical treatment on clinical symptoms severity as well as nerve and muscle cord changes of patients with carpal tunnel syndrome in moderate grade.**

### Protocol summary

#### Study aim

Evaluation of the effect of leech on treatment of patients with carpal tunnel syndrome in moderate grade.

#### Design

Two arm parallel group randomized trial with blinded assessor and analyzer. Block Randomization was computerized with concealed randomization sequence carried out with Spss Software

#### Settings and conduct

Study will be done at the 5 Azar educational Hospital and Health Center of Golestan University of Medical Sciences in field of Iranian traditional medicine. Patients are selected via convenience sampling. After performing the nerve and muscle strip and examination of the nerve system by neurologist, if they are qualify for entrance criteria, they allocated to control (drug therapy and cock-up splint) and intervention groups (drug therapy, cock-up splint and leech therapy) according to blocked random assignment.

#### Participants/Inclusion and exclusion criteria

Entry criterion: The presence of clinical symptoms and having positive Tinel, Fallen and carpal compersion tests Having positive paraclinical findings detected by electrodiagnosis in intermediate grades. Age between 30-60 years No entry criteria: Diseases that immitate CTS symptoms Non-fracture or repeated trauma to the wrist and wrist surgery Non-injection of intra-articular corticosteroid in the wrists during the past 3 months

#### Intervention groups

Patients are divided into two groups of control and intervention group. In the control group, the patient receives medical treatment (drug and short cock-up splint) but in the intervention group, the patient is also treated with leeches in addition to receiving medication and splint.

#### Main outcome variables

Nerve and muscle test strip changes, pain score, severity

of clinical symptoms

### General information

#### Reason for update

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180909040977N1**

Registration date: **2019-01-08, 1397/10/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2019-01-08, 1397/10/18**

Update count: **0**

#### Registration date

2019-01-08, 1397/10/18

#### Registrant information

##### Name

Ali akbar Aghaeinejad

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 17 3252 3631

##### Email address

dr.aghaeinejad@goums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2018-11-22, 1397/09/01

#### Expected recruitment end date

2019-11-22, 1398/09/01

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

A comparison between leech therapy and medical treatment on clinical symptoms severity as well as nerve and muscle cord changes of patients with carpal tunnel syndrome in moderate grade.

## Public title

The effect of leech therapy on carpal tunnel syndrome

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

The presence of clinical symptoms and having positive Tinel, Fallen and carpal compersion tests Having positive paraclinical findings (nerve conduction velocity and electromyography) detected by electrodiagnosis and the grades must be in intermediate level by neurologist and neurologist specialist diagnosis. Satisfaction should be gained by the use of one of two methods. Age between 30-60 years

### Exclusion criteria:

The presence of rheumatic disease, rheumatoid arthritis and other upper limb disorders, coagulation problems, diabetes, hypothyroidism, gout, lupus erythematosus, acromegaly, chronic kidney failure, and diseases that impede CTS symptoms. Pregnancy for up to a year and mental retardation and anemia Frequent fracture or trauma to the wrist and wrist surgery Injection of intra-articular corticosteroid in the wrists during the past 3 months Immune system disorders, severe allergic allergy, use of neuropathic drugs, use of non-steroidal anti-inflammatory drugs during the last two weeks History of stroke syndrome

## Age

From **30 years** old to **60 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Outcome assessor
- Data analyser

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, patients will be allocated to intervention and control groups based on four blocks randomization. The four blocks are entered into the SPSS software, and by mean of the "select random sample" field in SPSS, a one block randomly will be selected.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

In this study, data analyzer and an assessor who asks questionnaire on the 30th day from patient via telephone are blinded.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Golestan University of Medical Sciences

##### Street address

The beginning of the road is Shastcolaa

##### City

Gorgan

##### Province

Golestan

##### Postal code

4934174515

#### Approval date

2018-07-29, 1397/05/07

#### Ethics committee reference number

IR.GOUMS.REC.1397.098

## Health conditions studied

### 1

#### Description of health condition studied

The effect of leech therapy on Nerve condition in carpal tunnel syndrome patients

#### ICD-10 code

G56.1

#### ICD-10 code description

Other lesions of median nerve

## Primary outcomes

### 1

#### Description

Abnormalities in electromyography and nerve study

#### Timepoint

Once on the first day of the study and once on day 60.

#### Method of measurement

Electromyographic machine Nihon kohden model

### 2

#### Description

Pain score on the analog scale visual pain

#### Timepoint

In 4 steps, at the beginning of the study (before treatment or leech therapy), on day 15, day 30 and day

#### Method of measurement

Visual Analogue Scale

### 3

#### **Description**

Severity of symptoms and functional status

#### **Timepoint**

In 4 stages, at the time of entering the study (before treatment or leech therapy), on day 15, day 30 and day 60

#### **Method of measurement**

Boston Clinical Symptom Intensity Questionnaire

### **Secondary outcomes**

empty

### **Intervention groups**

#### 1

#### **Description**

Intervention group: In the intervention group, the patient uses leech therapy in addition to receiving medical treatment (Tablets of Celecoxib 100 mg twice daily, Gabapentin 100 mg twice daily, vitamin B; 300 mg once daily for one month, using short cock-up splint, which should be used at bedtime). Leech therapy will be implemented once, on the first day and in the absence of improvement of pain and clinical symptoms will be used for the second time on the 15th day with the diagnosis of Iranian medicine expert. Four leeches will be placed on the wrist, on anatomical pathway of the medial nerve.

#### **Category**

Treatment - Other

#### 2

#### **Description**

In the control group: the patient was treated purely with medical treatment, including tablets of Celecoxib 100 mg twice daily, Gabapentin 100 mg twice daily, vitamin B; 300 mg once daily for one month, plus a short cock up splint during sleep will be received.

#### **Category**

Treatment - Drugs

### **Recruitment centers**

#### 1

#### **Recruitment center**

##### **Name of recruitment center**

5 Azar Hospital

##### **Full name of responsible person**

Rozbe Shams amiri

##### **Street address**

5 Azar Street

##### **City**

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Rshamsa@gmail.com

### **Sponsors / Funding sources**

#### 1

#### **Sponsor**

##### **Name of organization / entity**

Gorgan University of Medical Sciences

##### **Full name of responsible person**

Mohamad reza honarvar

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Beginning of Shastkala Road

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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**

Gorgan 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**

Gorgan University of Medical Sciences

##### **Full name of responsible person**

Ali akbar Aghaeinejad

##### **Position**

Academic instructor

##### **Latest degree**

Master

##### **Other areas of specialty/work**

Nursery

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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dr.aghaeinejad@goums.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Decision making in this regard is based on patient information data. By considering the confidentiality of information, decided to publish patient information by the authors will be done at the end of the study.

Therefore, a program for the dissemination of information does not exist now

### 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