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

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Name of organization / entity

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Iran (Islamic Republic of)

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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
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Sponsors / Funding sources

1

Sponsor
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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
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Ali akbar Aghaeinejad
Position
Academic instructor
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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