Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of leech therapy in diabetic neuropathy of lower limbs

Protocol summary

Study aim
Evaluation of leech therapy in diabetic neuropathy of lower limbs

Design
Randomized clinical trial with parallel groups, phase 3, with 40 patients, with control group (standard treatment). Due to the type of treatment in this study, blindness is not possible. randomization is done using table of random numbers.

Settings and conduct
In the leech treatment group, 3 to 5 medical leeches with size of 6 to 8 cm for each foot are thrown each 15 days for 3 times and in the medication group, 300 mg gabapentin capsule are administered single dose at night before going to bed for 30 days. This study is performed in the traditional medicine health center of Babol University of Medical Sciences.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Having informed consent; Age 30 years and older; Type 2 diabetes with the approval of an endocrinologist; Diabetic neuropathy based on nerve and muscle tape; The patient should not use other drugs that affect neuropathy; No pregnancy; No breastfeeding; Lack of other diseases that cause neuropathy. Exclusion criteria: Diabetic ulcer requires surgery; Use of anticoagulants; Having any type of coagulation disease; Hospitalization history for cardiovascular disease; History of major mental disorders; Do not take painkillers or common medications for neuropathy treatment during the past month; Having anemia

Intervention groups
Case patients (leech therapy) and control (gabapentin)

Main outcome variables
Severity of pain, burning, tingling

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150927024228N3**
Registration date: **2020-10-22, 1399/08/01**
Registration timing: **registered_while_recruiting**

Last update: **2020-10-22, 1399/08/01**
Update count: **0**

Registration date
2020-10-22, 1399/08/01

Registrant information

Name
Maryam Azimi

Name of organization / entity
Kerman University Of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 34 3312 2020

Email address
m_azimidehali@collegian.kmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-04, 1399/05/14

Expected recruitment end date
2021-03-04, 1399/12/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of leech therapy in diabetic neuropathy of lower limbs

Public title
Evaluation of leech therapy in diabetic neuropathy of lower limbs

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having informed consent Age 30 years and above Type 2 diabetes with the approval of an endocrinologist Having diabetic neuropathy based on nerve and muscle tape The patient should not use other drugs that are effective on neuropathy at the same time No pregnancy No breastfeeding No other diseases that cause neuropathy such as alcohol, vitamin B12 deficiency, chemotherapy, kidney failure, nerve compression, autoimmune disease, infection, Guillain-Barre syndrome
Exclusion criteria:
Having a diabetic foot ulcer requires surgery Use of anticoagulants such as heparin, warfarin, etc Any coagulation disease History of hospitalization due to cardiovascular disease History of major mental disorders Not taking painkillers, or common drugs for neuropathy treatment during the last month Anemia
Age
From **30 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is done in a simple way using a table of random numbers. Among the numbers 1 to 40, 20 random numbers are selected from this table for the leech therapy and the rest (of the patients) are assigned to the standard treatment group. Patients are not known in advance. In this way, the order of entering the groups is determined: for example, it is pre-determined and it is written in the envelopes, for example, which group the 5th, 30th or 40th person will be in. When each person enters the study, an envelope is opened and the treatment group is determined for him. Sorting is done using a table of random numbers. some envelopes are provided according to the number of samples and the type of treatment is written in each envelope. We start reading from a point on the table of random numbers vertically and in two digits two digits. If the read number was between 01 and 40, the number is assigned to the leech therapy group. We will continue this work until we reach the number of samples in this group (20 people). the envelopes are closed and sealed and a three-digit code is written on each of them. the order of the envelopes is determined by a statistician. after the patient enters the study and completes the informed consent form, an envelope is opened and the type of treatment is determined; then the patient receives the treatment.
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 Committee of Kerman University of Medical Sciences
Street address
Shafa Crossroad, Jomhuri Boulevard, Kerman
City
Kerman
Province
Kerman
Postal code
7617633759
Approval date
2020-08-04, 1399/05/14
Ethics committee reference number
IR.KMU.REC.1399.317

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy
ICD-10 code
E11.40
ICD-10 code description
Type 2 diabetes mellitus with diabetic neuropathy, unspecified

Primary outcomes

1

Description
burning sensation
Timepoint
At the beginning of the study, days 15, 30 and 45 of the beginning of the study
Method of measurement
Using Visual Analogue Scale and Neurophathy Symptom Score questionnaires

2

Description
intensity of pain
Timepoint
At the beginning of the study, days 15, 30 and 45 of the

beginning of the study

Method of measurement

Using Visual Analogue Scale and Neurophathy Symptom Score questionnaires

3

Description

tingling

Timepoint

At the beginning of the study, days 15, 30 and 45 of the beginning of the study

Method of measurement

Visual Analogue scale and neuropathy symptom score questionnaire

Secondary outcomes

1

Description

Muscle weakness and cramps

Timepoint

At the beginning of the study, days 15, 30 and 45 after the start of the study

Method of measurement

Neoropathy Symptom Score questionnaire

2

Description

Vibration in the big toe

Timepoint

At the beginning of the study, days 15, 30 and 45 after the start of the study

Method of measurement

Neurophathy Disability Score questionnaire

3

Description

Recognize the feeling of cold and heat in the back of the legs

Timepoint

At the beginning of the study, days 15, 30 and 45 after the start of the study

Method of measurement

Neurophathy Disability Score questionnaire

4

Description

Detect sharp and blunt bodies on the big toe

Timepoint

At the beginning of the study, days 15, 30 and 45 after the start of the study

Method of measurement

Neurophathy Disability Score questionnaire

5

Description

Presence or absence of Achilles reflex

Timepoint

At the beginning of the study, days 15, 30 and 45 after the start of the study

Method of measurement

Neurophathy Disabilities score questionnaire

6

Description

Possible repair of foot nerves in its treatment with leeches

Timepoint

Before the start of the study and 45 days after the start of the study

Method of measurement

Nerve conduction velocity

7

Description

Possible repair of foot nerves in drug treatment

Timepoint

Before the start of the study and 45 days after the start of the study

Method of measurement

Nerve conduction velocity

Intervention groups

1

Description

In the leech treatment group, three to five medical leeches, six to eight centimeters in size, are thrown in three steps every fifteen days in the area of the back of the feet, tangentially from the root of the second toe to the external malleolus.

Category

Other

2

Description

In the control group, patients are given 300 mg of gabapentin capsule as a single dose at night before going to bed for 30 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Traditional Medicine Health Center of Babol University of Medical Sciences

Full name of responsible person

Farshad Alami

Street address

Nasiraei 8, Sardaran 9, Sheilh Tabaresi street

City

Babol
Province
Mazandaran
Postal code
4713937679
Phone
+98 11 3229 2492
Email
farshad.alami1700@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Abbas Pardakhti
Street address
Shafa Crossroad, Jolhuri Boulevard, Kerman
City
Kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3132 5041
Email
Abpardakhty@Kmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Kerman 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
Kerman University of Medical Sciences
Full name of responsible person
Farshad Alami
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Nasiraei8, Sardaran 9, Sheikh Tabarsi Street
City
Babol
Province
Mazandaran
Postal code
4713937679
Phone
+98 11 3229 2492
Email
farshad.alami1700@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Maryam Azimi
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Amirkabir Crossroad, Jomhuri Boulevard, Kerman
City
kerman
Province
Kerman
Postal code
7616913555
Phone
+98 34 3211 0123
Email
Dr.azimm@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Farshad Alami
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
Street address
Nasiraei8, Sardaran9, Sheikh Tabarsi Street
City
Babol
Province
Mazandaran
Postal code
4713937679

Phone
+98 11 3229 2492
Email
farshad.alami1700@gmail.com

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
Undecided - It is not yet known if there will be 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
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
Title and more details about the data/document
After the study, information about the main outcome will be shared.
When the data will become available and for how long
12 months after printing
To whom data/document is available
All researchers can get it.
Under which criteria data/document could be used
Data and results will be available to all researchers for research on diabetic neuropathy.
From where data/document is obtainable
dr.azimm@gmail.com
What processes are involved for a request to access data/document
The data will be provided to the applicant within one month after reviewing and confirming the application.
Comments