Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

The effect of Ghost oil on the treatment and relief of pain caused by diabetic neuropathy in a double-blind, parallel-controlled randomized clinical trial

Protocol summary

Study aim
Determining the effect of Ghost oil on the treatment and relief of pain caused by diabetic neuropathy

Design
Clinical trial with control group and with parallel groups, double-blind, randomized, phase 3, on 86 patients. To randomization the site https://www.sealedenvelope.com will be used.

Settings and conduct
The location of the study will be the personal office of an endocrinologist. 86 patients will be included in the study after being diagnosed with neuropathy with the main complaint of tingling and numbness and scoring 4 or higher on the neuropathy questionnaire by an endocrinologist and other inclusion criteria. Then they will be randomly assigned to two groups. The study is double-blind and neither the patients nor the evaluating doctor will know the type of treatment received.

Participants/Inclusion and exclusion criteria
Inclusion criteria: tingling in the area, pain in the distal region of the lower extremities, clinical diagnosis, type 2 diabetes, age over 18, chronic neuropathy; Exclusion criteria: limb pain due to other diseases, Drug-allergy, use of other drugs, addiction, use of anticoagulants, fractures, autoimmunity

Intervention groups
For one month, in the intervention group, Gabapentin 100 mg capsules will be used once a day and Ghost oil (made by Bo Ali Daru Company) will be used twice a day, in the morning before breakfast and at night before going to bed will be rubbed on the pain area and spine in a thin layer. The control group will be treated in the same way as the intervention group, only they will receive a placebo instead of the Ghost oil, which is completely similar to the Ghost oil.

Main outcome variables
pain score, quality of life

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220305054184N2**
Registration date: **2022-07-15, 1401/04/24**
Registration timing: **prospective**

Last update: **2022-07-15, 1401/04/24**
Update count: **0**

Registration date
2022-07-15, 1401/04/24

Registrant information

Name
Saleh Merati

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2022-09-23, 1401/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Ghost oil on the treatment and relief of pain caused by diabetic neuropathy in a double-blind, parallel-controlled randomized clinical trial

Public title
The effect of Ghost oil on the treatment and relief of pain caused by diabetic neuropathy

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
The main complaint of tingling Pain in the distal region of the lower limb for at least 3 months Clinical diagnosis of painful diabetic poly neuropathy plus a minimum score equal to or higher than 4 in the clinical evaluation of diabetic neuropathy (DN4 – Questionnaire) History of type 2 diabetes for at least 3 years Age over 18 years Chronic diabetic neuropathy

Exclusion criteria:
Lower limb pain caused by other diseases such as peripheral vascular disease and radiculopathy History of skin allergies to herbs Diabetic foot ulcers Taking other medications to treat diabetic neuropathy Drug addiction Taking anticoagulants Fractures and traumatic injuries lead to sensory and motor injuries in the lower extremities Autoimmune diseases (rheumatism and MS) History of hereditary neuropathies or underlying diseases that cause neuropathy such as chronic uremia lower limb amputation

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **86**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were assigned in to placebo or Ghost group using a permuted block randomization with block sizes of 4 and 6. The random sequence will be generated by a third person who had not any operational role in the study using a computer and the website https://www.sealedenvelope.com. In order to concealment, each patient will be assigned a unique code, and only the person who created the sequence will know which patient it belongs to.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study has been double-blind, Neither the patients nor the person evaluating the patients will know the type of treatment. In order to perform blindness, the treatments and treatment methods are exactly the same in the two groups and placebo will be used in the control group. The drugs of the two groups are in the form of oil and have the same color and are poured in the same containers and in the same shape. The codes are recorded on the drug labels, which are marked based on block randomization.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Kermanshah University of Medical Sciences

Street address
Vice Chancellor for Research and Technology, Building No. 2, Kermanshah University of Medical Sciences, Shahid Beheshti Blvd.

City
Kermanshah

Province
Kermanshah

Postal code
6714869914

Approval date
2021-04-27, 1400/02/07

Ethics committee reference number
IR.KUMS.REC.1400.108

Health conditions studied

1

Description of health condition studied
diabetic neuropathy

ICD-10 code
E13.43

ICD-10 code description
Other specified diabetes mellitus with diabetic autonomic (poly)neuropathy

Primary outcomes

1

Description
Pain score

Timepoint
In the present study, the time intervals for measuring the pain score variable would be before the start of the study and again one month after treatment in each group.

Method of measurement
McGill Questionnaire

2

Description
Quality of Life
Timepoint
In the present study, the time periods for measuring the quality of life variable would be before the start of the study and again one month after treatment in each group.
Method of measurement
World Health Organization Quality of Life Questionnaire (WHOQOL-BREF)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: For one month, in the intervention group, Gabapentin 100 mg capsules will be used once a day and Ghost oil (made by Bo Ali Daru Company) will be rubbed twice a day, in the morning before breakfast and at night before going to bed on the pain area and spine in a thin layer.
Category
Prevention

2

Description
Control group: For one month, in the control group, Gabapentin 100 mg capsules will be used once a day and placebo (made by Bo Ali Daru Company) will be rubbed twice a day, in the morning before breakfast and at night before going to bed on the pain area and spine in a thin layer.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Mehrad Doctors Building, Dr. Nasrin Moradian Office
Full name of responsible person
Dr. Nasrin Moradian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Kermanshah 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
Kermanshah University of Medical Sciences
Full name of responsible person
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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