Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Survey of effect of topical herbal medicine (neurohelp) on the treatment of diabetic neuropathy: a Randomized Clinical Trial

Protocol summary

Study aim
Determination of the effect of topical herbal medicine (neuroleptic) on the treatment of painful diabetic neuropathy

Design
Two arm parallel group trial with placebo control group and Block Randomization.

Settings and conduct
Setting of study: Diabetes Clinic of Shaheed Sayyad Shirazi Educational Hospital and 5 Azar Hospital of Gorgan. 70 patients with type 2 diabetes (eligible for inclusion) were randomly assigned to the control group (standard treatment + placebo) and the intervention group (standard treatment + Neurohelp). The outcome variables (Pain, Tingling, HbA1c, etc.) will be measured in 4 groups in both groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients with type 2 diabetes with uncontrolled blood glucose and between the ages of 30-70 years who have diabetic peripheral neuropathy are included in the study. Patients with daily pain for more than 3 months (VAS score>=4) are included in this study. Exclusion criteria: Drug and alcohol users, other causes for neuropathy , liver and kidney failure (serum creatinine> 1.5, LFT disorder (ALT, AST, total bilirubin, direct and alkaline phosphate), and disturbances in sodium electrolytes, Potassium, calcium), pregnancy or lactation, ulcers or foot infections, and complete patient insufficiency.

Intervention groups
Group B: Common treatment (Gabapentin and vitamins) + Liver tumor. Group A: Common treatment (Gabapentin and vitamins) + placebo

Main outcome variables
Pain score, Tingling score, numbness score

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20170422033566N2**
Registration date: **2018-06-25, 1397/04/04**
Registration timing: **registered_while_recruiting**

Last update: **2018-06-25, 1397/04/04**
Update count: **0**

Registration date
2018-06-25, 1397/04/04

Registrant information

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Fatemeh Mehravar

Name of organization / entity
Golestan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-19, 1397/01/30

Expected recruitment end date
2018-10-22, 1397/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Survey of effect of topical herbal medicine (neurohelp) on the treatment of diabetic neuropathy: a Randomized

Clinical Trial

Public title
Survey of effect of topical herbal medicine (neurohelp) on the treatment of diabetic neuropathy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with type 2 diabetes with uncontrolled blood sugar diabetic peripheral neuropathy aged between 30-70 years
Exclusion criteria:
Drug and alcohol users Other reasons for the development of neuropathy, liver and kidney failure Disruption of sodium, potassium, calcium electrolytes Pregnancy or breastfeeding Wound or foot infections Lack of full awareness of patient
Age
From **30 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Block Randomization
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
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
هیرکان
City
gorgan
Province
Golestan
Postal code
4934174515
Approval date
2018-04-14, 1397/01/25
Ethics committee reference number
IR.GOUMS.REC.1397.001

Health conditions studied

1

Description of health condition studied
Diabetic neuropathy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Pain
Timepoint
At the beginning of the study, 2 weeks after the start of the study, 2 months and 3 months after the start of the study
Method of measurement
Visual Analogue Scale (VAS)

2

Description
FBS
Timepoint
At the beginning of the study, 2 weeks after the start of the study, 2 months and 3 months after the start of the study
Method of measurement
by glucose oxidase method

3

Description
2HPR
Timepoint
At the beginning of the study, 2 weeks after the start of the study, 2 months and 3 months after the start of the study
Method of measurement
by glucose oxidase method

4

Description
B/S4PM
Timepoint
At the beginning of the study, 2 weeks after the start of the study, 2 months and 3 months after the start of the study
Method of measurement
by glucose oxidase method

5

Description

Tingling
Timepoint
At the beginning of the study, 2 weeks after the start of the study, 2 months and 3 months after the start of the study
Method of measurement
Visual Analogue Scale (VAS)

6

Description
numb
Timepoint
At the beginning of the study, 2 weeks after the start of the study, 2 months and 3 months after the start of the study
Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

1

Description
HbA1C
Timepoint
Start the study, three months after the intervention
Method of measurement
Blood glucose testing will be done using the Pars Test Kit and the HbA1C Assay with Diaz Kit with the diory 1200 automatic device.

Intervention groups

1

Description
Intervention group: Standard treatment (Gabapentin and Vitamins) + liquid synthetic neurohelp.
Category
Treatment - Drugs

2

Description
Control group: Standard treatment (Gabapentin and Vitamins) + Placebo
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Clinic of Shahid Sayyid Shirazi Hospital
Full name of responsible person
Maryam Zahedi
Street address
Sayad Shirazi Avem, Hospital
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4934174515
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Orman.nezam@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Mohammadreza Honarvar
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Hirkan Ave
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GOUMS_UNI@goums.ac.ir
Web page address
http://goums.ac.ir/
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
Ourman Nezami Narjabad
Position
Resident
Latest degree

Medical doctor
Other areas of specialty/work
Internal Medicine
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Person responsible for updating data

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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