

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Fatemeh Mehravar

Name of organization / entity

Golestan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 912 893 7199

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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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Email

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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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 scientific inquiries

Contact

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Full name of responsible person

Maryam Zahedi

Position

Assistant Professor

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Other areas of specialty/work

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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