

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of gabapentin and evening primrose oil with gabapentin and placebo on the pain of peripheral neuropathy in patients with type 2 diabetes.

Protocol summary

Study aim

Comparison of the effect of gabapentin and golden oil of gabapentin and placebo on the severity of pain due to peripheral neuropathy in two groups of intervention and control group Comparison of the effect of gabapentin and golden oil of gabapentin and placebo on the duration of pain caused by peripheral neuropathy in two groups of intervention and control group Comparison of the effect of gabapentin and golden oil of gabapentin and placebo on the quality of pain caused by peripheral neuropathy in the intervention group and the control group

Design

In this study, patients with diabetes neuropathy who are eligible for inclusion in the study who are referred to the Diabetes Clinic are selected. Participants are divided into two intervention and control groups based on permutation blocks.

Settings and conduct

The present study is a triple blind clinical trial study. So that the subjects and the researcher will be unaware of the type of drug they receive, and the statistician will have access to the data coded by the supervisor. The researcher referred to Diabetes Clinic of Neyshabur in 96 years after obtaining the necessary preparation for the research and obtaining a formal introduction from Sabzevar University of Medical Sciences. After introducing and expressing the purpose of the study, type 2 diabetic patients referred to the Diabetes Clinic During the monthly visits, there are complaints about neuropathy and then they are examined by a specialist physician and if there are clinical signs of polyneuropathy for introduction into the study.

Participants/Inclusion and exclusion criteria

Entry requirements The history of diabetes for at least 5 years There is a pain for more than three months No entry Presence of ulcer in the leg Infection in the foot

Intervention groups

The intervention group is treated with Olive oil at a dose of 1000 mg twice daily for three months and gabapentin (300 mg) daily. The control group was treated with gabapentin mg (300) and placebo twice a day for three months.

Main outcome variables

Intensity of pain Duration of pain Olive oil Age gender Duration of diabetes Cigarette blood pressure Pain quality

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171212037853N1**

Registration date: **2018-01-30, 1396/11/10**

Registration timing: **registered_while_recruiting**

Last update: **2018-01-30, 1396/11/10**

Update count: **0**

Registration date

2018-01-30, 1396/11/10

Registrant information

Name

zohre nasrabadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4263 8003

Email address

nasrz1@nums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of gabapentin and evening primrose oil with gabapentin and placebo on the pain of peripheral neuropathy in patients with type 2 diabetes.

Public title

Effect of Flower Magnum Oil on Diabetes Mellitus Neuropathy.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with diabetic neuropathy

Exclusion criteria:

All diabetic patients with heart failure All diabetic patients with renal failure

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: 70

Randomization (investigator's opinion)

Randomized

Randomization description

Qualified individuals are divided into two intervention and control groups based on randomized blocks.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Subjects and researchers will be unaware of the type of drug they receive, and the statistician will have access to the data coded by the supervisor.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Sabzevar University of Medical Sciences

Street address

Tawhid Township

City

Sabzevar

Province

Razavi Khorasan

Postal code

کد پستی: 9613873136

Approval date

2017-11-22, 1396/09/01

Ethics committee reference number

IR.MEDSAB.REC.1396.75

Health conditions studied**1****Description of health condition studied**

Diabetic neuropathy

ICD-10 code

E11.42

ICD-10 code description

Type 2 diabetes mellitus with diabetic polyneuropathy

Primary outcomes**1****Description**

Pain Score in McGill's Revised Questionnaire (SF-MPQ-2)

Timepoint

Measuring the pain before the intervention and after the intervention

Method of measurement

Revised McGill Pain Questionnaire (SF-MPQ-2)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: The intervention group is treated with Olive oil at a dose of 1000 mg twice a day for three months and gabapentin (300 mg) one night. Magnesium oil is produced by Barij Essence Company.

Category

Treatment - Drugs

2

Description

Control group: The control group is treated with gabapentin (300) mg per day and placebo twice a day for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic

Full name of responsible person

Souqandi Safiyah

Street address

Hakim Hospital, Khayyam Clinic

City

Neyshabour

Province

Razavi Khorasan

Postal code

93177-58489

Phone

+98 51 4263 8001

Email

NASRZ1@NUMS.AC.IR

Web page address

<https://portal.num.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sabzevar University of Medical Sciences

Full name of responsible person

Curt Fereshte

Street address

Deputy of Research and Technology of the University of Medical Sciences Campus, Boulevard Nuclear Martyrs, Above the Memorial of the Anonymous Martyrs

City

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VCRResearch@medsab.ac.ir

Web page address

<http://www.medsab.ac.ir>

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Sabzevar 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

Sabzevar University of Medical Sciences

Full name of responsible person

Nasrabadi Zohre

Position

Masters student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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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

Yes - There is 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

Yes - There is 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

All data can be shared after unidentifiable

When the data will become available and for how long

Six months after printing results

To whom data/document is available

Researchers of academic and academic institutions

Under which criteria data/document could be used

It is allowed to use any kind of analysis on the data

Allowed to use data in studies conducted in Iran

From where data/document is obtainable

Zohreh Nasrabadi E-mail nasrabadizohre6@gmail.com

What processes are involved for a request to access data/document

The request will be made by email. After the examination, the applicant will be answered.

Comments