

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the efficacy of topical Nigella Sativa product and gabapentin capsule on diabetic peripheral neuropathy

Protocol summary

Study aim

Determining and comparing the mean score of neuropathy severity in study groups: topical Nigella Sativa product, placebo (topical) and gabapentin capsule

Design

A randomized controlled clinical trial with parallel, double-blind, randomized groups

Settings and conduct

The study will be conducted at the Yazd Diabetes Research Center. Patients will be diagnosed by a neurologist. We then randomly divide the participants into three groups. The first group will receive topical Nigella Sativa (ointment), the second group topical placebo and the last group will receive gabapentin 300 mg capsules. Patients will be followed for 8 weeks. The first follow-up is at the end of the second week (to check for complications and adherence of patients) and the second follow-up is at the end of the fourth week and the third follow-up is at the end of the 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Type 2 diabetes mellitus with diabetic neuropathy diagnosed by neurologist resident of Yazd controlled glucose (HbA1c less than 9) exclusion criteria : Spinal Disorders and Discopathy Heart disorder Renal disorder Liver disorder Active foot ulcer Autoimmune diseases mental illnesses Drug and alcohol addiction Skin diseases in the area of drug use Severe foot vascular disorders

Intervention groups

The first group : topical Nigella Sativa (ointment) The second group : topical placebo (ointment) The last group : gabapentin 300 mg

Main outcome variables

Severity of neuropathy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160221026684N2**

Registration date: **2022-02-22, 1400/12/03**

Registration timing: **retrospective**

Last update: **2022-02-22, 1400/12/03**

Update count: **0**

Registration date

2022-02-22, 1400/12/03

Registrant information

Name

Seyed Ali Khodaie

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2022-02-19, 1400/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the efficacy of topical Nigella Sativa product and gabapentin capsule on diabetic peripheral neuropathy

Public title

The effect of Nigella Sativa on diabetic neuropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes mellitus with diabetic neuropathy diagnosed by neurologist resident of Yazd controlled glucose (HbA1c less than 9)

Exclusion criteria:

Spinal Disorders and Discopathy Heart disorder Renal disorder Liver disorder Active foot ulcer Autoimmune diseases mental illnesses Drug and alcohol addiction Skin diseases in the area of drug use Severe foot vascular disorders

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Random method: Simple random Random double blind Referral by a neurologist 120 envelopes: 40 pieces A (treatment), 40 pieces B (placebo), 40 pieces C (gabapentin) sealed and closed, in front of the secretary. Upon arrival, each patient is given a random envelope. The secretary only provides packages containing materials A, B and C to patients and does not know their contents.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, only the principal investigator and outcome assessor are aware of the contents of the envelope. Patients and others involved in the design have no information about the type of material in the envelopes. Drug and placebo are similar in shape, color, odor, packaging, and appearance, and blinding has been performed between them. Gabapentin capsule group is the standard treatment.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of shahid sadoughi university of medical sciences

Street address

Diabetes Research Center, Talar-e-Honar Alley, Shahid Sadoughi Blvd, Yazd

City

yazd

Province

Yazd

Postal code

8917693571

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.SSU.REC.1398.077

Health conditions studied

1

Description of health condition studied

diabetic neuropathy

ICD-10 code

E08.40

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description

Severity of peripheral neuropathy

Timepoint

before intervention and 2, 4 , 8 weeks after intervention

Method of measurement

MICHIGAN NEUROPATHY SCREENING INSTRUMENT

Secondary outcomes

1

Description

HbA1c

Timepoint

before intervention and 8 weeks after intervention

Method of measurement

Chromatography (HPLC)

Intervention groups

1

Description

First intervention group: topical Nigella Sativa product. This product is prepared from aqueous extract of black seed and base cream in the form of 10% ointment, used twice a day (morning and night before bed) and for 8 weeks on both patients' feet. The amount of ointment used each time is the size of a fingertip, which is massaged from top to bottom. The drug is formulated in Behdanebaran pharmaceutical company.

Category

Treatment - Drugs

2**Description**

Control group: topical placebo- This product is prepared from a base cream and black paint in the form of an ointment, used twice a day (morning and night before bed) and for 8 weeks on both patients' feet. The amount of ointment used each time is the size of a fingertip, which is massaged from top to bottom. The placebo is formulated in Behdanebaran pharmaceutical company

Category

Placebo

3**Description**

Second intervention group: Gabapentin 300 mg capsules- In this group, patients receive a 300 mg gabapentin capsule orally every night before bed for 8 weeks. Capsules are manufactured by JALINOUS Pharmaceutical Company.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetes Research Center

Full name of responsible person

seyedalikhodaie

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Talar-e-Hanar Alley, North Shahid Sadoughi Blvd

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Yazd University of Medical Sciences

Full name of responsible person

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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

Yazd 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**

Yazd University of Medical Sciences

Full name of responsible person

seyedalikhodaie

Position

Non-Academic Specialist Physician

Latest degree

Ph.D.

Other areas of specialty/work

Traditional Medicine

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Title and more details about the data/document

Nigella Sativa data Data on the main outcome will be made available to other researchers with the permission of the first executor.

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Coordinate with project analyzer

From where data/document is obtainable

dr seyed ali khodaie :03537280215
dr.seyedalikhodaie@yahoo.com

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

Request data from Yazd University of Medical Sciences, approval of the director of the Diabetes Research Center, approval of the first executor of the project

Comments