Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparing the effectiveness of olive leaf extract and Pregabalin on symptomatic treatment of diabetic neuropathy

Protocol summary

Study aim
Determination of clinical efficacy of olive leaf compared to pregabalin in reducing the amount of pain caused by diabetic neuropathy by to 50% of the initial amount

Design
The study is randomized, double-blinded without placebo control and in clinical trial stage 1-2

Settings and conduct
Selection of patients is done at the Diabetes Clinic affiliated to Kermanshah University of Medical Sciences. Patients participating in research and researcher completing questionnaires are Unaware of used medication.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Type I and II diabetic patients with diabetes for at least one year who have diabetic neuropathy pain; History of neuropathic pain for at least three months; The pain (VAS) is equal to or greater than 4; Being at the age of 18 or over; HbA1c is equal to or less than 11; Non Inclusion criteria: Pregnant and lactating women; Patients who suffer from ischemic pain or other pain such as pain associated with amputation or arthritis; patients who have had Electroconvulsive Therapy in the past 30 days.

Intervention groups
Intervention group: the olive leaf extract three times a day for 3 months. Control group: pregabalin capsule, twice a day for three months.

Main outcome variables
Pain score on visual analog scale

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20100513003922N4**
Registration date: **2019-01-08, 1397/10/18**
Registration timing: **registered_while_recruiting**
Last update: **2019-05-25, 1398/03/04**
Update count: **1**

Registration date
2019-01-08, 1397/10/18

Registrant information

Name
Masoud Modarresi

Name of organization / entity
Faculty of Pharmacy - Kermanshah University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 83 1835 6168

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mmodarresi@kums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-12-22, 1397/10/01

Expected recruitment end date
2019-09-22, 1398/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effectiveness of olive leaf extract and Pregabalin on symptomatic treatment of diabetic neuropathy

Public title
Study of effect of olive leaves on diabetic neuropathy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type I and II diabetic patients who have diabetes for at least one year and have diabetic neuropathy pain History of neuropathic pain for at least three months a pain score (VSA) equal to or greater than 4 at least 18 years of age or older HbA1c is equal to or less than 11

Exclusion criteria:

Pregnant and lactating women ischemic pain or other pain such as pains associated with amputation or arthritis Electroconvulsive Therapy in the past 30 days using warfarin, antiarrhythmic drugs, sedatives, hypnotices, anticonvulsants, NSAIDs and capsaicin in the past 7 days using antipsychotics, antidepressants, opioids and muscle relaxants during the past 14 days using anti-neuropathic drug and Unwillingness to stop taking it Dependence on alcohol or other drugs important metabolic diseases, cardiovascular diseases, thyroid disease, major blood diseases, reduced kidney function or liver function, bipolar disease, psychosis history of suicide drug sensitivity

Age

From **18 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two treatment groups based on the table of randomized numbers. A point is selected from the table of randomized numbers. From that point, the displacement will be done to the right and in the direction of the horizon. Odd numbers are assigned to the chemical treatment group and even numbers are assigned to the herbal treatment group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients participating in the study are unaware of the type of drug they receive (herbal or chemical). In addition, the researcher completing the questionnaire is also unaware of the type of drug that the patient has received.

Placebo

Not 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

Building No. 2, Shaheed Beheshti Blvd

City

Kermanshah

Province

Kermanshah

Postal code

6714673159

Approval date

2018-11-14, 1397/08/23

Ethics committee reference number

IR.KUMS.REC.1397.581

Health conditions studied

1

Description of health condition studied

Diabetic neuropathy

ICD-10 code

E10.4

ICD-10 code description

Diabetic autonomic neuropathy

Primary outcomes

1

Description

Pain score on visual analog scale

Timepoint

At the end of each month for three consecutive months

Method of measurement

visual analog scale

Secondary outcomes

1

Description

quality of life score

Timepoint

At the beginning of the study and at the end of the third month of the study

Method of measurement

Quality of life questionnaire SF-36

2

Description

Diarrhea

Timepoint

during the study

Method of measurement
questionnaire of patient-reported side effects

3

Description
Stomach ache
Timepoint
during the study
Method of measurement
questionnaire of patient-reported side effects

Intervention groups

1

Description
Intervention group: Olive leaf extract (capsule) is given orally three times a day for three consecutive months.
Category
Treatment - Drugs

2

Description
Control group: Pregabalin is prescribed orally twice a day for three consecutive months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Diabetes Center of Kermanshah University of Medical Sciences
Full name of responsible person
Dr Rozita Nasseri
Street address
Near Taleghani Hospital, Shaheed Beheshti Blvd.
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6715847167
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+98 83 3836 2014
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kermanshah University of Medical Sciences
Full name of responsible person
Dr Farid Najafi
Street address
Building No. 2, Shaheed Beheshti Blvd
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6714673159
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farid_n32@yahoo.com
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
Dr Masoud Modarresi
Position
Member of the scientific board of the university / Associate Professor (Ph.D.)
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Faculty of Pharmacy, Parastar Blv., Daneshgah St., Shaheed Shiroodi Blv.
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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Kermanshah University of Medical Sciences

Full name of responsible person
Dr Masoud Modarresi

Position
Member of the scientific board of the university/ Associate Professor

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Person responsible for updating data

Contact

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Kermanshah University of Medical Sciences

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Pain scores and quality of life scores at the beginning and end of the study are shared.

When the data will become available and for how long
The access period starts 6 months after printing the results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
Compliance with professional ethics in the use of data

From where data/document is obtainable
Send an email to the responsible person

What processes are involved for a request to access data/document
After reviewing the qualifications of the requesting person, the information is sent to researcher by email at most three months.

Comments