

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 Jun 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)

###### Phone

+98 83 1835 6168

###### Email address

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, hypnotics, 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 Nasser

##### Street address

Near Taleghani Hospital, Shaheed Beheshti Blvd.

##### City

Kermanshah

##### Province

Kermanshah

##### Postal code

6715847167

##### Phone

+98 83 3836 2014

##### Email

rnasser.75@gmail.com

## 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

### City

Kermanshah

### Province

Kermanshah

### Postal code

6714673159

### Phone

+98 83 3838 4185

### Email

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.

#### City

Kermanshah

#### Province

Kermanshah

#### Postal code

6714415153

#### Phone

+98 83 3427 6482

#### Email

mmodarresi@kums.ac.ir

## 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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Ph.D.

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr Masoud Modarresi

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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**