

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jul 2026

### The effect of black seed oil massage on the severity of restless legs syndrome in patients with type 2 diabetes

#### Protocol summary

##### Study aim

Determining the effect of black seed oil massage on the severity of restless legs syndrome in patients with type 2 diabetes

##### Design

Clinical trial with control group, with parallel groups, one-way blind, randomized, phase 3-2 on 76 patients. For randomization, Sealed Envelope Ltd. software 2017 was used.

##### Settings and conduct

The samples studied in this study include all patients with moderate to severe foot syndrome who are hospitalized in Shahid Beheshti Hospital of Kashan University of Medical Sciences. The method of massage is such that each person after soaking the palms with black oil The bead (2 cc) with continuous pressure of the fingers starts the massage from the toes and then the sole of the foot and gradually continues to the top of the knee. In the control group, only routine and routine actions will be performed.

##### Participants/Inclusion and exclusion criteria

Having type 2 diabetes, No diabetic foot ulcers, Lack of allergy to black seed oil, no use of sleeping pills and psychiatric drugs, No heart, lung or brain disease

##### Intervention groups

Intervention group: In addition to the usual and routine treatments such as pramipexole and cabergoline, gabapentin, benzodiazepines, ibuprofen and codeine, massage the feet with black seed oil overnight for 40 nights. Control group: Only conventional and routine treatments such as pramipexole and receive cabergoline, gabapentin, benzodiazepines, ibuprofen and codeine.

##### Main outcome variables

Severity of restless leg syndrome

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20100211003329N8**

Registration date: **2022-02-24, 1400/12/05**

Registration timing: **prospective**

Last update: **2022-03-11, 1400/12/20**

Update count: **1**

##### Registration date

2022-02-24, 1400/12/05

#### Registrant information

##### Name

Zahra Sooki

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 5554 0021

##### Email address

sooki\_z@kaums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2022-03-06, 1400/12/15

#### Expected recruitment end date

2022-04-19, 1401/01/30

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of black seed oil massage on the severity of restless legs syndrome in patients with type 2 diabetes

#### Public title

The effect of black seed oil massage on the severity of restless legs syndrome in patients with type 2 diabetes

## **Purpose**

Supportive

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

Willingness to participate in research and conscious satisfaction Having type 2 diabetes Lack of sensitivity to black seed oil Do not take sleeping pills and psychiatric drugs

### **Exclusion criteria:**

diabetic foot ulcers heart, lung or brain disease

## **Age**

No age limit

## **Gender**

Both

## **Phase**

2-3

## **Groups that have been masked**

- Outcome assessor
- Data analyser

## **Sample size**

Target sample size: **76**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

How to select the samples will be randomly assigned to each of the two intervention and comparison groups in block, 4, 6 and 8 blocks. Using Sealed Envelope Ltd. software. 2017 Through the site [www.sealedenvelope.com](http://www.sealedenvelope.com) 3 blocks of 4, 6 blocks of 6 and 4 blocks of 8, a total of 13 blocks (In the form of a number) were defined, which will be assigned to groups according to the order specified by the tool.

## **Blinding (investigator's opinion)**

Single blinded

## **Blinding description**

Outcome assessors and analyzer are unaware of the effect of black seed oil massage on Restless Legs Syndrome in type 2 diabetic patients.

## **Placebo**

Not used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Kashan University of Medical Sciences

##### **Street address**

Kashan. Qutb Ravandi Blvd., Pezeshk Blvd., Kashan

University of Medical Sciences

## **City**

Kashan

## **Province**

Isfahan

## **Postal code**

87155981151

## **Approval date**

2022-02-07, 1400/11/18

## **Ethics committee reference number**

IR.KAUMS.NUHEPM.REC.1400.064

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Restless legs Syndrom

#### **ICD-10 code**

G25.81

#### **ICD-10 code description**

Restless legs syndrome

### 2

#### **Description of health condition studied**

Diabetes Type 2

#### **ICD-10 code**

E11

#### **ICD-10 code description**

Type 2 diabetes mellitus

## **Primary outcomes**

### 1

#### **Description**

Severity of restlessness leg syndrome

#### **Timepoint**

Before the intervention, after the intervention

#### **Method of measurement**

Using the standard Restless Legs Syndrome checklist

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: The subject and objectives of the study are explained for each of participants, and if she/he wish to participate in the study, a questionnaire for diagnosing Restless Legs Syndrome and a checklist of demographic information for patients will be completed. It should be noted that skin sensitivity of individuals to study is also examined. For this purpose, 5 cc of black seed oil is massaged on the person's skin with the desired purity, and in case of any symptoms of erythema, inflammation, blisters and other symptoms of

skin allergies, while eliminating the person's symptoms, it will be removed from the study. Eligible individuals (earning a score of 11 or higher according to the IRLSS checklist) after being selected and obtaining consent to participate in the study, are introduced, reviewed, and randomly entered to study. In the intervention group for 40 nights, one night in between, before going to bed, black seed oil prepared from Barij Essential Oil Company with a purity of 5%, in the amount of 2 cc is used for each foot (a total of 80 cc for each participant should be considered). Will give, and for heterosexual participants, the male colleague will be helped to train the male participants and do it once. The method of massage is such that each person Applying black palm oil (2 cc) on the palms of the hands, continuously massaging the fingers from the toes, then the soles of the feet and gradually continuing to the top of the knees. At the end of the intervention, restlessness questionnaires were completed for patients in both groups.

#### Category

Treatment - Drugs

## 2

#### Description

Control group: In the control group, only routine treatments (Take drugs such as pramipexole and cabergoline, gabapentin, benzodiazepines, ibuprofen and codeine) will be performed

#### Category

Treatment - Drugs

## Recruitment centers

## 1

#### Recruitment center

##### Name of recruitment center

Kashan Shahid Beheshti hospital

##### Full name of responsible person

Zohre Khalaj

##### Street address

Ghotb Ravandi

##### City

Kashan

##### Province

Isfahan

##### Postal code

87159 88111

##### Phone

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##### Email

z.sooki@yahoo.com

## Sponsors / Funding sources

## 1

#### Sponsor

Name of organization / entity

Kashan University of Medical Sciences

#### Full name of responsible person

Dr Hamidreza Banafsheh

#### Street address

Ghotb Ravandi

#### City

Kashan

#### Province

Isfahan

#### Postal code

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#### Email

banafsheh\_h@kaums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Kashan 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

Kashan University of Medical Sciences

##### Full name of responsible person

Mansour Dianati

##### Position

Assistant Professor

##### Latest degree

Ph.D.

##### Other areas of specialty/work

Nursery

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## Person responsible for updating data

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**Other areas of specialty/work**  
Reproductive Health

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

### Justification/reason for indecision/not sharing IPD

Not done yet

### 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

No - There is not 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