

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Efficacy and safety of Lavender aromatherapy on sleep quality and metabolic parameters of patients with diabetes mellitus type II and insomnia

#### Protocol summary

##### Summary

Considering the high prevalence of sleep disturbance in diabetic patients and the effectiveness of lavender oil in sleep disorders in this study, the effect of lavender on sleep disorders and metabolic factors in type 2 diabetes patients will be studied. This study is designed as Cross-over double-blind placebo-controlled randomized clinical trial. 40 patients with diabetic type 2 and sleep disorder with the inclusion criteria will enter into the study and randomly assign to first intervention group and first placebo group. The patients in intervention group pour 3 drops of Lavender essential oil on a cotton wool then smell it rhythmic and slowly for 5 minutes at bed time for 4 weeks and the placebo group pour 3 drops of placebo oil on a cotton wool then smell it rhythmic and slowly for 5 minutes at bed time for 4 week. After 1 week washout the patients will be crossed-over. Some inclusion criteria are age between 25-65 years old, Fasting Blood Sugar between 70-130, 2 hour post prandial glucose less than 180, HbA1C less than 7 and Sleep disorder according to Pittsburgh Insomnia Rating Scale more than 5. Some exclusion criteria are any systemic illnesses, Use of sedative or antidepressant drugs, Anosmia, History of allergic reaction to Lavender and headache that start with smell. Primary outcome will be changed in sleep disorder and also metabolic parameters.

#### General information

##### Acronym

Lavender aromatherapy in diabetic patient with sleep disorders

##### IRCT registration information

IRCT registration number: **IRCT201703117297N3**  
Registration date: **2017-10-21, 1396/07/29**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-10-21, 1396/07/29

##### Registrant information

###### Name

Mojtaba Heydari

###### Name of organization / entity

Shiraz university of medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 71 1235 7679

###### Email address

mheydari@sums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Shiraz University of Medical Sciences

##### Expected recruitment start date

2017-08-20, 1396/05/29

##### Expected recruitment end date

2018-02-18, 1396/11/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy and safety of Lavender aromatherapy on sleep quality and metabolic parameters of patients with diabetes mellitus type II and insomnia

##### Public title

Efficacy and safety of Lavender aromatherapy on sleep

quality and metabolic parameters of patients with diabetes mellitus type II and insomnia

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

Inclusion criteria: • Age: 25-65 years old. Fasting Blood Sugar between 70-130. 2 hour post prandial glucose less than 180. HbA1C less than 7. Sleep disorder according to pittsburgh Insomnia Rating Scale more than 5. Exclusion criteria: Any systemic illnesses. Use of sedative or antidepressant drugs. Pregnancy. Lactation. History of allergic reaction to Lavender. History of allergic rhinitis, asthma and respiratory disorders. Anosmia. Headache that start with smell. Cigarette smoking or substance abuse. Hospitalization or surgery within 1 months ago.

### **Age**

From **25 years** old to **65 years** old

### **Gender**

Both

### **Phase**

N/A

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **40**

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

Randomized

### **Randomization description**

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

Double blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Crossover

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

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

Research Deputy of Shiraz University of Medical Sciences, Shiraz, Iran.

##### **Street address**

Zand Avenue. Central building Shiraz University of Medical Sciences, Shiraz, Iran.

##### **City**

Shiraz

##### **Postal code**

71345-1978

#### **Approval date**

2017-02-28, 1395/12/10

#### **Ethics committee reference number**

IR.SUMS.REC.1395.191

## **Health conditions studied**

### 1

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

diabetes-insomnia

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

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

## **Primary outcomes**

### 1

#### **Description**

pittsburgh Insomnia Rating Scale

#### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

#### **Method of measurement**

pittsburgh Insomnia Rating Scale

## **Secondary outcomes**

### 1

#### **Description**

CRP

#### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

#### **Method of measurement**

Blood sample

### 2

#### **Description**

FBS

#### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

#### **Method of measurement**

blood sample

### 3

#### **Description**

TG

#### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

#### **Method of measurement**

blood sample

### 4

#### **Description**

Cholesterol

#### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

#### **Method of measurement**

blood sample

## 5

### **Description**

LDL

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

blood sample

## 6

### **Description**

HDL

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

blood sample

## 7

### **Description**

2hPPG

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

blood sample

## 8

### **Description**

Serum Insulin

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

blood sample

## 9

### **Description**

AST

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

blood sample

## 10

### **Description**

ALT

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

blood sample

## 11

### **Description**

height

## **Timepoint**

before intervention

### **Method of measurement**

meter

## 12

### **Description**

weight

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

weight scale

## 13

### **Description**

BMI

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

BMI Index

## 14

### **Description**

waist circumference

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

meter

## 15

### **Description**

Hip circumference

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

meter

## 16

### **Description**

HbA1C

### **Timepoint**

before intervention

### **Method of measurement**

Blood sample

## 17

### **Description**

Cr

### **Timepoint**

before intervention- 4 week after drug- 4 week after placebo

### **Method of measurement**

Blood sample

## 18

### Description

Uric acid

### Timepoint

before intervention- 4 week after drug- 4 week after placebo

### Method of measurement

Blood sample

## 19

### Description

BP

### Timepoint

before intervention- 4 week after drug- 4 week after placebo

### Method of measurement

Sphygmomanometer

## Intervention groups

### 1

#### Description

Lavender Essential oil

#### Category

Treatment - Drugs

### 2

#### Description

almond oil

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Motahhari Clinic, Shiraz University of Medical Sciences

##### Full name of responsible person

zeinab nasiri lari

##### Street address

Shahid Motahhari Clinic, Shiraz University of Medical Sciences

##### City

Shiraz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Dr Seyed Basir Hashemi

##### Street address

Zand Av, Shiraz University of Medical Sciences

##### City

Shiraz

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Shiraz University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Dr Mojtaba Heydari

#### Position

MD,Ph.D Assistant professor in Traditional Persian Medicine

#### Other areas of specialty/work

#### Street address

Zand Avenue. Central building Shiraz University of Medical Sciences, Shiraz, Iran.

#### City

Shiraz

#### Postal code

71345-1978

#### Phone

+98 71 3235 7282

#### Fax

+98 32307594

#### Email

vcrdep@sums.ac.ir

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Shiraz University of Medical Sciences

#### Full name of responsible person

Mesbah Shams, M.D. Associate professor of Internal medicine and Endocrinology

#### Position

Associate professor of Internal medicine and Endocrinology, Shiraz University of Medical Sciences

#### Other areas of specialty/work

#### Street address

zand Av, Shiraz University of Medical Sciences

**City**

Shiraz

**Postal code**

71345- 1978

**Phone**

+98 71 3235 7282

**Fax**

+98 32307594

**Email**

vcrdep@sums.ac.ir Shams@sums.ac.ir

meshkat\_114@yahoo.com

**Web page address**

Shiraz

**Postal code**

71345-1978

**Phone**

+98 71 3235 7282

**Fax**

+98 32307594

**Email**

dr.znasiri@gmail.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Zeinab Nasiri Lari

**Position**

MD, Ph.D student in Traditional Persian Medicine

**Other areas of specialty/work**

**Street address**

Zand AV, Shiraz University of Medical Sciences

**City**

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*