

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