Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of Lavandula angustifolia efficacy in treatment of depression in diabetic patients of Shiraz

Protocol summary

Study aim
Promoting quality of life and health of diabetic patients

Design
Eligible patients will be consciously referred to the Shahid Motahari clinic of Shiraz University of Medical Sciences and will be divided into intervention and control groups by block randomization method. The minimum sample size was determined 30 in each group.

Settings and conduct
The patients will be referred to Shahid Motahari Clinic and after the evaluation of inclusion criteria, they will be assessed by Beck, Pittsburgh and WHO-5 Well-being Index questionnaires and the biochemical parameters will be measured. Then the drugs are given free for 8 weeks. At the end of the study, the questionnaires will be completed and biochemical variables will be measured again and side effects will also be noted.

Participants/Inclusion and exclusion criteria
inclusion criteria: Type 1 or 2 controlled diabetes(70 <FBS <130 and 2hppG <180); Age over 18 years old; A history of over 3 months of depression based on Beck's Questionnaire; Satisfaction of participation; no usage of the drugs which are out of the study protocol; Patients with mild to moderate depression based on the Beck criteria (score less than 28). exclusion criteria: Pregnancy; Lactation; Systemic unstable diseases; having any illness affecting the variables; active suicidal thoughts;

Intervention groups
Patients in the intervention group: Sertraline capsule with dosage of 50 mg qhs for 1 week and then 100 mg qhs till the end of the study and a capsule containing 200 mg essential oil of lavender qhs Patients Control group: Sertraline capsule with dosage of 50 mg qhs for 1 week and then 100 mg qhs till the end of the study and a placebo capsule

Main outcome variables
Change in Beck Depression Inventory Score; The rate of change in Pittsburgh Insomnia Questionnaire score; Change in the WHO-5 Well-being Index Questionnaire score; The rate of change in biochemical variables

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150309021386N2**
Registration date: **2018-07-15, 1397/04/24**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-15, 1397/04/24**
Update count: **0**

Registration date
2018-07-15, 1397/04/24

Registrant information

Name
Mohaddese Ostovar

Name of organization / entity
Shiraz University of Medical Sciences

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-06-22, 1397/04/01

Expected recruitment end date
2018-10-23, 1397/08/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Lavandula angustifolia efficacy in treatment of depression in diabetic patients of Shiraz

Public title

Effect of Lavender in treatment of depression in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 1 or 2 diabetes mellitus that is controlled (70 <FBS <130 and 2hppG <180) • Age over 18 years old• Over 3-months history of depression based on Beck's questionnaire • Satisfaction with participating in the study • No usage of out-of-study protocol treatments (all anti-depressant drugs (TCA, SSRI, SNRI, etc.) and medicinal herbs affecting mood such as bell peppermint, valerian fever, and lemon balm, etc.) • Patients who have mild to moderate depression based on the Beck criteria (score less than 28)

Exclusion criteria:

Pregnancy, Lactation, Systemic unstable diseases (liver, thyroid, cardiovascular, renal dx), Active suicidal thoughts

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Before filling the bottles with either drug or placebo capsule, the they were divided into two equal groups according to the random numbers table. The bottles were then filled with drugs or placebo based on the results obtained.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Before filling the bottles with either drug or placebo capsule, the they were divided into two equal groups according to the random numbers table. The bottles were then filled with drugs or placebo based on the results obtained. Only the researcher can decode the contents of each bottle based on the original form of the randomization. The person responsible for the delivery of the drug, the patient, the physician, and the person responsible for evaluating the consequences, will not be informed of the coding . The results of the control and intervention groups under the headings A and B will be delivered to the statistical analyst.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand street

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2018-06-18, 1397/03/28

Ethics committee reference number

IR.SUMS.MED.REC.1397.134

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.1

ICD-10 code description

Major Depressive Disorder, single episode, moderate

2

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 Diabetes Mellitus

3

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E10

ICD-10 code description

Type 1 Diabetes Mellitus

Primary outcomes

1

Description

Change in Beck Depression Inventory Score

Timepoint

At The Beginning And at The End of The Study

Method of measurement

Beck Depression Questionnaire

Secondary outcomes

1

Description

Pittsburgh Insomnia Questionnaire

Timepoint

At The Beginning and at The End of The Study

Method of measurement

Pittsburgh Insomnia Questionnaire

2

Description

Change of WHO-5 Well-being Index Questionnaire Score

Timepoint

At The Beginning and at The End of The Study

Method of measurement

WHO-5 Well-being Index Questionnaire

3

Description

Change of Biochemical Variables

Timepoint

At The Beginning and at The End of The Study

Method of measurement

Laboratory Data

Intervention groups

1

Description

Intervention group: Sertraline capsule qhs with dosage of 50 mg for 1 week and then 100 mg till the end of the study plus one gelatin capsule containing 200mg of lavender essential oil qhs

Category

Treatment - Drugs

2

Description

Control group: Sertraline capsule qhs with dosage of 50 mg for 1 week and then 100 mg till the end of the study plus one placebo capsule qhs.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari clinic in Shiraz

Full name of responsible person

Mohadeseh Ostovar

Street address

zand street

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shiraz

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

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7134814336

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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

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
Shiraz University of Medical Sciences
Full name of responsible person
Mohadesel Ostovar
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
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Person responsible for scientific inquiries

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assistant professor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
Beck Depression , Petersberg insomnia, WHO5 Well Being questionnaire and Biochemical Variables Only part of the data on the primary outcome can be shared.
When the data will become available and for how long
data will be accessed 6 months after publication of the results
To whom data/document is available
Only available to scholars working in academic institutes
Under which criteria data/document could be used
Only part of the documentation can be provided to scholars from academic and clinical centers and with official permission from Shiraz University of Medical Sciences.
From where data/document is obtainable
Vice Chancellor of Research Postal Address: Vice-Chancellor for Research, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran Postal Code: 71345-1978 Tel: +98 71 32357282 Fax: +98 71 32307594 E-mail: vcrdep@sums.ac.ir
What processes are involved for a request to access data/document

After sending the request to the Vice-Chancellor for Research of Shiraz University of Medical Sciences, this request will be assessed and if approved by the relevant vice president, the planner will be informed to disseminate the data. Then the data will be provided to him.

Comments