

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of lemon balm extract on depression, anxiety, sleep quality and hs-CRP in comparison with control group in patients with type II diabetes and depression

Protocol summary

Summary

This study aims to investigate the effect of Melissa officinalis extract on depression, anxiety, sleep quality and hs-CRP in comparison with control group in patients with type II diabetes and depression. In this randomized double-blinded placebo-control clinical trial 60 patients with type 2 diabetes with depression referring to the Institute of Endocrinology and Metabolism will be included. Inclusion criteria are: getting at least 11 scores in the Beck Depression Inventory (BDI-II); Patients aged 20 to 65 years for both sexes; The body mass index less than 35 kg/m²; no pregnancy or lactation; triglycerides less than 400 mg/dl; HbA1c < % 8; using a common diabetes drug (metformin and glibenclamide). Exclusion criteria are: Lack of any co-disorders including cardiovascular, liver, renal, allergic and infectious diseases as well as thyroid disorders and glaucoma; taking non steroidal anti-inflammatory drugs (NSAIDS), anti depression or estrogen and progesterone. Patients will be randomly assigned to intervention or control groups. In intervention group, patients will receive capsules containing 350 mg Melissa officinalis extract twice per day for 3 months. While, patients at the control group will receive placebo capsules containing 350 mg toasted flour twice daily during 3 months. All laboratory test including fasting blood sugar and hs-CRP , in addition Severity of depression and anxiety (by Beck inventory for depression and anxiety), sleep quality (by Pittsburgh sleep quality questionnaire), blood pressure and anthropometric indices will be measured at baseline and week 12 of the study. Also, the dietary intakes and physical activity will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201709239472N16**

Registration date: **2017-10-09, 1396/07/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-10-09, 1396/07/17

Registrant information

Name

Naheed Aryaeian

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 8670 4750

Email address

aryaeian.n@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

private sector

Expected recruitment start date

2017-10-23, 1396/08/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of lemon balm extract on depression, anxiety,

sleep quality and hs-CRP in comparison with control group in patients with type II diabetes and depression

Public title
Effects of lemon balm extract on depression, anxiety, sleep quality and hs-CRP in comparison with control group in patients with type II diabetes and depression

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria are: getting at least 11 scores in the Beck Depression Inventory (BDI-II); Patients aged 20 to 65 years for both sexes; The body mass index less than 35 kg/m²; no pregnancy or lactation; triglycerides less than 400 mg/dl; HbA1c < % 8; using a common diabetes drug (metformin and glibenclamide). Exclusion criteria are: Lack of any co-disorders including cardiovascular, liver, renal, allergic and infectious diseases as well as thyroid disorders and glaucoma; taking non steroidal anti-inflammatory drugs (NSAIDS), anti depression or estrogen and progesterone.

Age
From **20 years** old to **65 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
The patients will be categorized in three groups by random allocation.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Iran University Of Medical Science
Street address
Hemmat highway,Tehran,Iran
City
Tehran
Postal code
Approval date

2017-08-28, 1396/06/06
Ethics committee reference number
IR.IUMS.FMD.REC 1396.9413468004

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E10, E11,
ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Sleep quality
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Pittsburgh Sleep Quality Index

2

Description
Depression
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Beck Depression Questionnaire

3

Description
FBS
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Enzymatic method

4

Description
hs-CRP
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
ELISA

5

Description
Anxiety
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Beck Anxiety Questionnaire

Secondary outcomes

1

Description

BP

Timepoint

Before the experiment and 12 weeks after intervention

Method of measurement

Digital sphygmomanometer

2

Description

Body mass index

Timepoint

Before the experiment and 12 weeks after intervention

Method of measurement

Weight (kg) /height² (m²)

3

Description

Weight

Timepoint

Before the experiment and 12 weeks after intervention

Method of measurement

Seca scale

4

Description

Waist circumference

Timepoint

Before the experiment and 12 weeks after intervention

Method of measurement

Elastic tape

5

Description

Physical activity

Timepoint

Before intervention and 6 and 12 weeks after intervention

Method of measurement

International Physical Activity Questionnaire

6

Description

Energy intake

Timepoint

Before intervention and 6 and 12 weeks after intervention

Method of measurement

24-hour dietary recall

Intervention groups

1

Description

Intervention group: Taking orally 2 herbal capsules of 350 mg melissa officinalis extract per day (one after Lunch and one after Dinner) for 3 months. Capsules are provided in Institute of Medicinal Plants affiliated with ACECR

Category

Treatment - Drugs

2

Description

Placebo group: Taking orally 2 similar capsules of toasted flour per day for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

The Institute of Endocrinology and Metabolism Research (Iran University Of Medical Sciences)

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

private

Full name of responsible person

Mostafa Safari

Street address

Iran University of Medical Sciences, next to the Tower and Milad Hospital, Hemmat Highway

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

private

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

Iran University Medical of Sciences

Full name of responsible person

Mostafa Safari

Position

Student Masters

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University Medical of Sciences

Full name of responsible person

Nahid Aryaeian

Position

associate professor

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Web page address

Person responsible for updating data

Contact

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