Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Effects of lemon balm extract on glycemic criteria, lipid profile, apolipoprotein B, apolipoprotein A-1, antioxidant capacity and hs-CRP in comparison with control group in patients with type II diabetes

Protocol summary

Study aim

This study aims to investigate the effect of Melissa officinalis extract on glycemic status, lipid profile, apolipoprotein B, apolipoprotein A1, total antioxidant capacity and hs-CRP in patients with type II diabetes.

Design

Patients will be randomly assigned two groups. In the intervention group, patients will receive two capsules containing 350 mg Melissa officinalis extract per day for 3 months. patients in the control group will receive two capsules containing 350 mg toasted flour twice daily for 3 months. Laboratory tests including glycemic status, lipid profile, apolipoprotein B, apolipoprotein A1, total antioxidant capacity and hs-CRP , also blood pressure and anthropometric indices will be measured at baseline and at the end study. Also, the dietary intakes and physical activity will be measured.

Settings and conduct

In this randomized double-blinded placebo-control clinical trial 70 patients with type 2 diabetes referring to the Iranian Diabetes Society and Institute of Endocrinology and Metabolism will be included.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: Patients aged 20 to 65 years for both sexes; BMI less than 35 kg/m2; no pregnancy or lactation; TG less than 400 mg/dl; HbA1c < % 8; using oral hypoglycemic agents. Exclusion criteria are: possess of any co-disorders including cardiovascular, liver, renal, allergic and infectious diseases as well as thyroid disorders and glaucoma; taking NSAIDS drugs or estrogen and progesterone.

Intervention groups

Intervention group: Taking orally 2 capsules of 350 mg Mellissa officinalis extract per day for 3 months. Capsules are provided in Institute of Medicinal Plants affiliated with ACECR. Placebo group: Taking orally 2 similar capsules of toasted flour.

Main outcome variables

FBS, Fasting insulin, Total antioxidant capacity, Apo A-1, Apo B, HbA1c, TG, TC, HDL-C, LDL-C, hs-CRP, Insulin resistance (HOMA-IR)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT201701162709N41**
Registration date: **2017-05-17, 1396/02/27**
Registration timing: **prospective**

Last update: **2018-03-25, 1397/01/05**
Update count: **1**

Registration date

2017-05-17, 1396/02/27

Registrant information

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Farzad Shidfar
Name of organization / entity
Iran University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Iran University Of Medical Sciences

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date
2017-08-23, 1396/06/01
Actual recruitment start date
2017-05-22, 1396/03/01
Actual recruitment end date
2017-11-01, 1396/08/10
Trial completion date
empty

Scientific title
Effects of lemon balm extract on glycemic criteria, lipid profile, apolipoprotein B, apolipoprotein A-1, antioxidant capacity and hs-CRP in comparison with control group in patients with type II diabetes

Public title
Effects of lemon balm extract on glycemic criteria, lipid profile, hs-CRP and antioxidant status in patients with type II diabetes
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria are: 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) or estrogen and progesterone.
Exclusion criteria:
Age
From **20 years** old to **65 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: **70**
Actual sample size reached: **62**
Randomization (investigator's opinion)
Randomized
Randomization description
The patients will be categorized in two groups by random allocation.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients will be categorized into three groups by random allocation.
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
Ethics committee of Iran University of Medical Sciences
Street address
Iran University Of Medical Science, Hemmat highway,Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1449614535
Approval date
2017-01-09, 1395/10/20
Ethics committee reference number
IR.IUMS.REC 1395.9411468001

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

2

Description
Fasting insulin
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
ELISA

3

Description
Total antioxidant capacity
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Colorimetry (FRAP)

4

Description
Apo A-1
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Immunoturbidimetry

5

Description
Apo B
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Immunoturbidimetry

6

Description
HbA1c
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
High Performance Liquid Chromatography

7

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

8

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

9

Description
HDL-C
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Enzymatic method

10

Description
LDL-C
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Friedewald formula

11

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

12

Description
Insulin resistance (HOMA-IR)
Timepoint
before the experiment and 12 weeks after intervention
Method of measurement
Formula

Secondary outcomes

1

Description
BP
Timepoint
Before the experiment and 12 weeks after intervention
Method of measurement
Mercury 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 Questionarre

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 mellissa 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
Iraj Heidary
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Endocrine and Research Center-Firozgar Education Center-Behafarin Avenue-Valiasr Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for Research, Iran University Of Medical Sciences
Full name of responsible person
Dr. Seyed Ali Javad Moosavi
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7th Floor, Department of Internal Medicine, Hazrat-E-Rasoul Hospital, Iran University of Medical Sciences, Niayesh St., Sattarkahn Ave, Tehran, Iran.
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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
Vice Chancellor for Research, Iran 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
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Farzad Shidfar
Position
Professor
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Other areas of specialty/work
Nutrition

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available