Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Effects of Melissa Officinalis L. on Lipid Profile in Patients with Hyperlipidemia

Protocol summary

Summary

Objectives, Design, Setting and conduct: The aim of this research is to determine the effects of Melissa Officinalis on lipid profile in Patients with Hyperlipidemia. This study is a randomized double-blind placebo-controlled clinical trial. The study conducted on 60 hyperlipidemic patients who were not in clinical range to taking other antihyperlipidemic agents. Major Inclusion and Exclusion criteria: Male and female aged 25 to 65 years with cholesterol levels 200 to 260 mg/dl who do not need to take of serum lipids lowering drugs were recruited randomly. The patients with diabetes, coronary vascular disease, renal, hepatic, hematological, pulmonary, uncontrolled hypertension and also pregnant women and breast-feeding women, patients using antihyperlipidemic agents, steroids, Cigarette, alcohol were excluded. Intervention: Treatment group received the grind powder of Melissa officinalis and control group received placebo capsules at a dose of 3 gr daily (two 500mg capsules after every main course) by the oral route for 2 months. main outcome variables: At baseline and also the end of the study, the fasting (after at least fasting for 12 h) blood serum

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014042017347N1**
Registration date: **2014-08-25, 1393/06/03**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-08-25, 1393/06/03

Registrant information

Name
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Name of organization / entity
Qazvin University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Qazvin University of Medical Sciences

Expected recruitment start date

2014-01-21, 1392/11/01

Expected recruitment end date

2014-07-23, 1393/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Melissa Officinalis L. on Lipid Profile in Patients with Hyperlipidemia

Public title

The Effect of Melissa Officinalis on Serum Lipid Profile

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: male and female outpatients aged 25 to 65 years; They had at least one of indices including Serum total cholesterol: 200 to 260 mg/dl; Serum low density lipoprotein: 100 to up mg/dl and Serum Triglycerides: 150 to 300 mg/dl; Body Mass Index (BMI) less than 40 Exclusion criteria: the patients who are in

need of taking other antihyperlipidemic agents; patient with diabetes; coronary-vascular disease; renal; hepatic; hematological; pulmonary diseases; Uncontrolled hypertension; pregnant women; breast-feeding women; women planning pregnancy; patients using antihyperlipidemic agents; steroids; Cigarette; alcohol; they who may suffer from undesirable complications over the study including headache; vertigo; Nausea and melissa officinalis intolerance; patients Unwillingness to cooperate with this study.

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

Gender
Both

Phase
2

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

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Qazvin University of Medical Sciences

Street address
Qazvin University of Medical Sciences, Shahid bahonar Boulevard, Qazvin,Iran

City
Qazvin

Postal code
3419759811

Approval date
2013-11-25, 1392/09/04

Ethics committee reference number
28.20.8098

Health conditions studied

1

Description of health condition studied
Hyperlipidemia

ICD-10 code
E78.5

ICD-10 code description
Hyperlipidaemia, unspecified

Primary outcomes

1

Description
Lipid profile:Total cholesterol, Triglyceride, HDL-C, LDL-C

Timepoint
Baseline and after two months

Method of measurement
Biochemical Analysis

2

Description
Liver Enzymes: ALT, AST

Timepoint
Baseline and after two months

Method of measurement
Biochemical Analysis

3

Description
Thyroid Hormones: T3, T4, TSH

Timepoint
Baseline and after two months

Method of measurement
Biochemical Analysis

4

Description
Fasting Blood Suger

Timepoint
Baseline and after two months

Method of measurement
Biochemical Analysis

5

Description
Creatinine

Timepoint
Baseline and after two months

Method of measurement
Biochemical Analysis

Secondary outcomes

1

Description
Side Effect

Timepoint
Baseline and after two months

Method of measurement
Checklist

2

Description
Body Mass Index
Timepoint
Baseline and after two months
Method of measurement
Formula

3

Description
Pulse Rate
Timepoint
Baseline and after two months
Method of measurement
Baseline and after two months

4

Description
Blood Pressure
Timepoint
Baseline and after two months
Method of measurement
Baseline and after two months

Intervention groups

1

Description
Intervention Group: grind powder of melissa officinalis at a dose of 3 gr daily (two 500mg capsules after every main course) by the oral route for two months
Category
Treatment - Drugs

2

Description
Control Group: grind powder of corn starch at a dose of 3 gr daily (two 500mg capsuls after every main course) by the oral route for two months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ansari Hospital
Full name of responsible person
Parisa Jandaghi
Street address
Narmak Day and Night Clinic, 46 west Ave, Narmak area, Tehran, Iran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Saeeid Asef Zadeh
Street address
Qazvin University of Medical Sciences, Shadid Bahonar Boulevard, Qazvin, Iran
City
Qazvin
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Qazvin 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
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Position
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Person responsible for scientific inquiries

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Parisa Jandaghi

Position

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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