

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Aug 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

Parisa Jandaghi

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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jandaghi.parisa@yahoo.com

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 Sugar

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 capsules 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. Saeed 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

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Mostafa Noroozi

Position

Associated Professor of Human Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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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