

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of Mellisa Officinalis on sleep disorders, depression, anxiety and stress, the result of exercise test, echocardiography, the level of MDA, hs-CRP, cardiovascular risk factors, and lipid profiles in patients who suffer from chronic stable angina

Protocol summary

Summary

Objective: Determination of the effect of Mellisa Officinalis on sleep disorders, depression, anxiety, stress, the result of exercise test, echocardiography, the level of MDA, hs-CRP, cardiovascular risk factors, and lipid profiles in patients who suffer from chronic stable angina
Design: randomized, double blind, placebo, treatment
Method: A: Population: -Inclusion criteria: patients (men and women) who suffer from chronic stable angina; age 40-75 yr; BMI 40-18.5 -Exclusion criteria: suffering from hypertension; diabete; aritmia; kidney disease; liver disease; blood disease; pulmonary disease; mascuskeletal disease; artrit rheumatism; inflammatory bowel disease; digestive disease; tyroid disorders; athletes; pregnants and lactating women; women who are willing to be pregnant; being on special diets such as vegetarianism; history of mellisa allergy; consumption of nutritional supplements, sedatives, smoking, alcohol; change in type or amount of medications, diet, and physical activity during the study; patients who suffer from complications such as headache, dizzines, nasia, and mellisa intolerance during the study; not willing to continue co-operation with the study -Sample size: 80 B: Intervention:Case group receives 3 gram mellisa suplement daily (1 capsule contains 1 gram mellisa after each meal), and control group receives 3 gram corn starch powder (1 capsule contains 1 gram corn starch powder after each meal). Duration of intervention: 2 months Outcomes: We expect that mellisa treats sleep disorder, depression, stress, anxiety, and improves the result of exercise test, echocardiography, and the level of MDA, hs-CRP, cardiovascular risk factors, and lipid profiles in patients who suffer from chronic stable angina.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016052928152N1**

Registration date: **2017-02-22, 1395/12/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-22, 1395/12/04

Registrant information

Name

Assieh Mohammadzadeh

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 3336 7543

Email address

mohammadzadeh.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jondishapour University of Medical Sciences

Expected recruitment start date

2016-04-08, 1395/01/20

Expected recruitment end date

2017-03-16, 1395/12/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of *Mellisa Officinalis* on sleep disorders, depression, anxiety and stress, the result of exercise test, echocardiography, the level of MDA, hs-CRP, cardiovascular risk factors, and lipid profiles in patients who suffer from chronic stable angina

Public title

The effect of *Mellisa Officinalis* on cardiovascular disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: suffering from chronic stable angina; age 40-75 yr; BMI 18.5-40; willing to co-operate
Exclusion criteria: suffering from hypertension; diabetes; arrhythmia; kidney disease; liver disease; blood disease; pulmonary disease; musculoskeletal diseases; arthritis; rheumatism; inflammatory bowel disease; digestive disease; thyroid disorders; athletes; pregnant and lactating women; women who are willing to be pregnant; being on special diets such as vegetarianism; history of *mellisa* allergy; consumption of nutritional supplements, sedatives, smoking, alcohol; change in type or amount of medications, diet, and physical activity during the study; patients who suffer from complications such as headache, dizziness, nausea, and *mellisa* intolerance during the study; not willing to continue co-operation with the study

Age

From **40 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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**

Ahvaz Jondishapour University of Medical Sciences

Street address

Ahvaz Jondishapour University of Medical Sciences-
Golestan BLV- Ahvaz

City

Ahvaz

Postal code**Approval date**

2017-01-14, 1395/10/25

Ethics committee reference number

IR.AJUMS.REC1395.592

Health conditions studied**1****Description of health condition studied**

Stable Chronic Angina

ICD-10 code

I20.1

ICD-10 code description

Angina pectoris with documented spasm

Primary outcomes**1****Description**

Lipid Profile

Timepoint

before intervention- at the end of intervention

Method of measurement

Blood Analysis

Secondary outcomes**1****Description**

LDH

Timepoint

before intervention- at the end of intervention

Method of measurement

blood analysis

2**Description**

hs-CRP

Timepoint

before intervention- at the end of intervention

Method of measurement

blood analysis

3**Description**

sleep disorder

Timepoint

before intervention- at the end of intervention

Method of measurement

Pittsburg sleep disorder questionnaire

4

Description

depression

Timepoint

before intervention- at the end of intervention

Method of measurement

Depression Anxiety Stress Scales (DASS)

5

Description

anxiety

Timepoint

before intervention- at the end of intervention

Method of measurement

Depression Anxiety Stress Scales (DASS)

6

Description

stress

Timepoint

before intervention- at the end of intervention

Method of measurement

Depression Anxiety Stress Scales (DASS)

7

Description

heart functional capacity

Timepoint

before intervention- at the end of intervention

Method of measurement

exercise test

8

Description

Ejection Fraction

Timepoint

before intervention- at the end of intervention

Method of measurement

echocardiography

9

Description

MDA

Timepoint

before intervention- at the end of intervention

Method of measurement

blood analysis

10

Description

NO

Timepoint

before intervention- at the end of intervention

Method of measurement

blood analysis

11

Description

Paraoxonase 1

Timepoint

before intervention- at the end of intervention

Method of measurement

blood analysis

Intervention groups

1

Description

Case group receives 3 gram mellisa suplement daily (1 capsule contains 1 gram mellisa after each meal) during two months

Category

Treatment - Drugs

2

Description

Control group receives 3 gram corn starch powder (1 capsule contains 1 gram corn starch powder after each meal) during two months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Echocardiography department-Golestan Hospital- Ahvaz

Full name of responsible person

Assieh Mohammadzadeh- PhD Candidate in Nutrition

Street address

Echocardiography department- Golestan Hospital- Golestan BLV- Ahvaz

City

Ahvaz

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Research Assistance, Ahvaz Jondishapour University of Medical Sciences

Full name of responsible person

Dr Behzad Sharif Makhmalzadeh

Street address

Research Assistance, Ahvaz Jondishapour University of Medical Sciences ,Golestan BLV, Ahvaz

City

Ahvaz

Grant name**Grant code / Reference number**

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

Yes

Title of funding source

Research Assistance, Ahvaz Jondishapur 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**

Ahvaz Jondishapur University of Medical Sciences

Full name of responsible person

Assieh Mohammadzadeh

Position

PhD Candidate in Nutrition

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

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Position

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Web page address**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