Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of Mellisa Officinalis on sleep disorders, depresion, 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 stabe angina

Protocol summary

Summary

Objective: Determination of the effect of Mellisa Officinalis on sleep disorders, depresion, 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 stabe 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; pulmunary disease; mascuskeletal disease; artrit rhematism; 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, alchohol; 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 stabe 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
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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, depresion, 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 stabe angina

Public title
The effect of Mellisa Officinalis on cardiovascular disease
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria: suffering from chronic stabe angina; age 40-75 yr; BMI 18.5-40; willing to co-operate
Exclusion criteria: suffering from hypertension; diabete; aritmia; kidney disease;liver disease;blood disease; pulmunary disease; mascuskeletal diseas; artrit rhematism; 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, alchohol; 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
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 Jondishapur 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 Jondishapour 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 Jondishapour University of Medical Sciences
Full name of responsible person
Assieh Mohammadzadeh
Position
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Person responsible for updating data

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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