

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Assessment of Satureja hortensis effect on serum glucose, LDL-cholesterol, HDL-cholesterol, triglyceride, hs-CRP and blood pressure in metabolic syndrome patients.

Protocol summary

Summary

The aim of this study is to assess the Satureja hortensis effects on metabolic syndrome. Inclusion criteria comprises: waist circumference for men ≥ 102 cm and for women ≥ 88 cm, fasting blood glucose ≥ 110 mg/dl, HDL-cholesterol for men < 40 mg/dl and for women < 50 mg/dl, Triglycerides ≥ 150 mg/dl, Blood pressure $\geq 130/85$ mm Hg. Exclusion criteria also considered as: liver dysfunction; smoking; kidney disorder; consumption of NSAIDs and incidence of any inflammatory disease. This double-blind randomized controlled clinical trial will be done on 60 metabolic syndrome patients (30 for placebo and 30 for intervention group) referred to Shiraz Imam Reza hospital for 7 weeks. Patient selection will be done by a third party in form of simple randomization in two groups of 1 or 2 (placebo or intervention). The patients' codes and group numbers will remain with the third party until the end of study when they will be used for analysis. Measurement of serum levels of glucose, LDL-cholesterol, HDL-cholesterol, triglyceride, hs-CRP and blood pressure will be done at the beginning of the study before treatment. Also at the end of study in day 70 after intervention with Satureja hortensis dry leaf 450 mg in a capsule per day in intervention group and placebo 450 mg in a capsule per day in placebo group, serum levels of aforementioned parameters will be measured again. Data obtained from measurements before and after intervention in both groups will be compared by SPSS software analyzing.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014012616372N1**

Registration date: **2014-02-26, 1392/12/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-02-26, 1392/12/07

Registrant information

Name

Farzad Nikaein

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vise Chancellor for Research Affairs, Shiraz University of Medical Sciences

Expected recruitment start date

2013-08-04, 1392/05/13

Expected recruitment end date

2013-11-21, 1392/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of Satureja hortensis effect on serum glucose, LDL-cholesterol, HDL-cholesterol, triglyceride, hs-CRP and blood pressure in metabolic syndrome patients.

Public title

Satureja hortensis effect on serum glucose, lipids, inflammatory factor and blood pressure in metabolic syndrome patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Waist circumference men ≥ 102 cm or 40in and women ≥ 88 cm or 35in, Fasting blood glucose ≥ 110 mg/dl, HDL-cholesterol for men < 40 mg/dl and for women < 50 mg/dl, Triglycerides ≥ 150 mg/dl, Blood pressure $\geq 130/85$ mm Hg. Exclusion criteria: hypothyroidism; alcoholism; smoking; auto immune disease; chronic pancreatitis; liver dysfunction; kidney disorder or nephritic syndrome; simultaneous subscription in other interventional study; any inflammatory disease or incidence of infection at start or during the study period; consumption of other drug such as aspirin, propranolol, NSAIDs, any form of steroids and any kind of blood glucose and lipid lowering agent; angioplasty or heart attack positive history; pregnancy and lactating.

Age

From **30 years** old

Gender

Both

Phase

3

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**

Shiraz University of Medical Sciences Ethics Committee

Street address

Shiraz University of Medical Sciences Ethics Committee, Zand st., Shiraz, Iran

City

Shiraz

Postal code**Approval date**

2013-09-28, 1392/07/06

Ethics committee reference number

92-6707

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

Metabolic Syndrome

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

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

Fasting Blood Glucose

Timepoint

Beginning of study first day and at the end of study 70th day

Method of measurement

Laboratory kit, Pars Azmoon

2**Description**

LDL-cholesterol

Timepoint

Beginning of study first day and at the end of study 70th day

Method of measurement

Laboratory kit, Pars Azmoon

3**Description**

High sensitive- C Reactive Protein

Timepoint

Beginning of study first day and at the end of study 70th day

Method of measurement

Laboratory kit, Pars Azmoon

4**Description**

Blood Pressure (systolic and diastolic)

Timepoint

Beginning of study first day and at the end of study 70th day

Method of measurement

Beurer Upper Arm Digital Blood Pressure Monitor

5**Description**

HDL-cholesterol

Timepoint

Begining of study first day and at the end of study 70th day

Method of measurement

Laboratory kit, Pars Azmoon

6**Description**

Triglyceride

Timepoint

Begining of study first day and at the end of study 70th dayBegining and end of study

Method of measurement

Laboratory kit, Pars Azmoon

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

Alanine Aminotransferase

Timepoint

Begining of study first day and at the end of study 70th day

Method of measurement

Laboratory kit, Pars Azmoon

2**Description**

Aspartate Aminotransferase

Timepoint

Begining of study first day and at the end of study 70th day

Method of measurement

Laboratory kit, Pars Azmoon

3**Description**

Complete Blood Count

Timepoint

Begining of study first day and at the end of study 70th day

Method of measurement

CBC counter machine, Sysmex

Intervention groups**1****Description**

Intervention group: Satureja hortensis dry leaf 450 mg in a capsule per day for 70 days

Category

Treatment - Drugs

2**Description**

Control group: Starch and green edible color 450 mg in a

capsule per day for 70 days

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Healthy Heart Institute

Full name of responsible person

Mrs. Maryam Rezaei

Street address

Healthy Heart Institute, Fazilat St., Modares Blvd., Shiraz, Iran

City

Shiraz

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs

Full name of responsible person

Dr. Ali Poostforush

Street address

Vice Chancellor for Research Affairs, Shiraz University of Medical Sciences, Zand Blvd., Shiraz, Iran

City

Shiraz

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Shiraz University of Medical Sciences, Vice Chancellor for Research Affairs

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**

School of Nutrition, Shiraz University of Medical Sciences

Full name of responsible person

Farzad Nikaein

Position

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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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