

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Clinical trial of the effect of aqueous extract of *Salvia mirzayani* in control of blood sugar of type 2 diabetic patients in comparison with control group

Protocol summary

Summary

The purpose of this study is to evaluate the effect of aqueous extract of *Salvia mirzayani* on the control of blood sugar in Type 2 diabetic patients. In this study, 58 Type 2 diabetic patients refer to diabetes clinic of Shahid Mohammadi Hospital, are divided into interventional and control groups. The interventional group receives capsules containing 450 mg of concentrated aqueous extract of *Salvia mirzayani* and the control group receives placebo capsules containing 450 mg of caramelized flour and 5% of aqueous extract of *Salvia mirzayani*. The inclusion criteria include patients with the age range between 19 and 65 years, who have BMI higher than 19 and lower than 30, patients with HbA1C higher than 7% and blood sugar higher than 126 mg/d. The exclusion criteria include pregnant women, patients with active infection or hepatitis, patients with blood pressure higher than 160/90 and cancer. The patients' demographic information such as age, sex, height, weight, body mass index, types and dosage of used drugs will be collected. The tests including determination of FBS, HbA1C, liver enzymes, lipid profile and serum insulin will be conducted at the beginning of the study and after 3 months. Serum will be separated from 5cc blood of fasting patients and the mentioned measurements will be performed and the results will be compared in the interventional and control groups. This clinical trial is double blind (neither the administrator nor the subject know which subjects receive a real drug or placebo).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015122725712N1**
Registration date: **2017-04-27, 1396/02/07**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-04-27, 1396/02/07

Registrant information

Name

Soheila Moein

Name of organization / entity

Hormozgan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Hormozgan University of Medical Sciences

Expected recruitment start date

2016-04-03, 1395/01/15

Expected recruitment end date

2016-07-05, 1395/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of aqueous extract of *Salvia mirzayani* in control of blood sugar of type 2 diabetic

patients in comparison with control group

Public title

Investigation the effect of aqueous extract of salvia mirzayanii in treatment of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria include patients with the age range between 19 and 65 years; patients having diabetes mellitus based on the guideline of the WHO 1999; Patients with BMI were >19 Kg/m² and <30 Kg/m²; Patients with BMI > 30, who have not any other diseases; Patients without insulin therapy and any other complications; Patients with HbA1C > 7% and blood sugar > 7 mmol/l Exclusion criteria's include pregnant women, or women wanted to become Pregnant; Patients with active infections or hepatitis C, B, HIV or TB (or in TB therapy); Cancer patients (except patients with skin cancer); patients using steroids such as prednisone for the treatment of a chronic disease; patients smoking cigarettes and drinking alcohol; patients with blood pressure higher than 160/90; usage of contraceptive pill by women; Moreover, patients with malabsorption; chronic diarrhea; liver and kidney diseases; ischemia heart failure; anemia; heart attack; peripheral vascular disease and diabetic nephropathy are excluded from the study.

Age

From **19 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

in the beginning of the study and after 3 months of intervention, randomization will be performed by using random number table

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Hormozgan University of Medical Sciences

Street address

Pardis of Hormozgan University of Medical Sciences , Emam Hossein BLVd, Bandarabbas

City

Bandarabbas

Postal code

Approval date

2015-09-23, 1394/07/01

Ethics committee reference number

HUMS.REC.1394.53

Health conditions studied

1

Description of health condition studied

Type 2 diabetes disease based on WHO guide line

ICD-10 code

E11

ICD-10 code description

Non insulin dependent diabetes

Primary outcomes

1

Description

HbA1C

Timepoint

in the beginnig of study and after 3 months of intervention

Method of measurement

by kit

2

Description

levels of liver enzymes

Timepoint

beginning of the study and after 3 months of intervention

Method of measurement

by kit

3

Description

lipid profile

Timepoint

beginning of the study and after 3 months of intervention

Method of measurement

by kit

4

Description

Fasting Blood Sugar(FBS)

Timepoint

in the beginnig of the study and after 3 months of intervention

Method of measurement

by kit

Secondary outcomes

1

Description

BMI

Timepoint

in the beginning of the study and after 3 months of intervention

Method of measurement

Balance

Intervention groups

1

Description

Interventional group: Every day one hour after lunch, patients of interventional group receive 1 capsule containing 450 mg of aqueous extract of *Salvia mirzayanii* for 3 months.

Category

Placebo

2

Description

Control group: Every day one hour after lunch, patients of this group receive 1 placebo capsule containing 450 mg of caramelized flour and 5% of aqueous extract of *Salvia mirzayanii* for 3 months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

diabetes clinic

Full name of responsible person

Leila Bahmanzadeh

Street address

Shahid Mohammadi Hospital

City

Bandarabbas

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hormozgan University of Medical Sciences

Full name of responsible person

Dr Aghamolaei

Street address

Vice chancellor for Research, Hormozgan University of Medical Sciences, Shahid Mohammadi Hospital

City

Bandarabbas

Grant name

-

Grant code / Reference number

94102

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

Yes

Title of funding source

Hormozgan 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

Hormozgan University of Medical Sciences

Full name of responsible person

Dr Soheila Moein

Position

Research assistant, Ph.D, Associate Professor

Other areas of specialty/work

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Research assistant, Ph.D, associate professor

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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