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 mirzayanii 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 mirzayanii and the control group receives placebo capsules containing 450 mg of caramelized flour and 5% of aqueous extract of Salvia mirzayanii. 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
Country
Iran (Islamic Republic of)
Phone
+98 763668476
Email address
smoein@sums.ac.ir

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 beginnig 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 Mohmmadi 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
Street address
Faculty of Medicine, Pardis of Hormozgan University of Medical Sciences, Emam Hossein BLVd
City
Bandarabbas
Postal code
7919693116
Phone
+98 76 3366 8476
Fax
+98 76 3366 8478
Email
soheila_9@yahoo.com; smoein@razi.tums.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Hormozgan University of Medical Sciences
Full name of responsible person
Soheila Moein
Position
Research assistant, Ph.D, associate professor
Other areas of specialty/work
Street address

Faculty of Medicine, Pardis of Hormozgan University of Medical Sciences, Emam Hossein BLVd

City
Bandarabbas

Postal code
7919693116

Phone
+98 76 3366 8476

Fax
+98 76 3366 8478

Email
soheila_9@yahoo.com; smoein@razi.tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Hormozgan University of Medical Sciences

Full name of responsible person
Rahman Mehdizadeh

Position
Research Ph.d candidate

Other areas of specialty/work

Street address
Faculty of Medicine, Pardis of Hormozgan University of Medical Sciences, Emam Hossein BLVd

City
Bandarabbas

Postal code
7919693116

Phone
+98 76 3366 8476

Fax
+98 76 3366 8476

Email
rahman.biochem@gmail.com

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