Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the Effectiveness of F. assa-foetida and Placebo on Antihyperglycemic, Antihyperlipidemic, Anti-inflammatory, and Antioxidant Activities in Type 2 Diabetes Mellitus Patients

Protocol summary

Study aim

Evaluation of antihyperglycemic, antihyperlipidemic, anti-inflammatory, and antioxidant effects of F. assa-foetida in type 2 diabetes

Design

A double-blind randomized, placebo-controlled clinical trial with a parallel groups design of 66 patients

Settings and conduct

Patients will be visited in four different situations: Visit 1: Screening and registration (Day 1): Anthropometric measurements, systolic and diastolic blood pressure (mmHg), dietary intake using Food frequency questionnaire (FFQ), and physical activity by physical activity measurement questionnaire will be evaluated. Visit 2: Randomization and blood Sampling (Day 2): 8 cc blood will be obtained in fasting, 60 capsules of Asafin or placebo are given to each patient and the patient will be asked to take a capsule before breakfast and dinner for 3 months. Visit 3 (Day 45): Anthropometric measurements, blood pressure, diet and physical activity will be measured. Visit 4 (day 90): 8 cc blood will be taken in fasting state. Then physical activity, anthropometry, blood pressure, and diet will be measured. The measures of ānthropometric, blood pressure, physical activity, and dietary intake are the confounding variables and compared between two groups.

Participants/Inclusion and exclusion criteria

Patients aged 25-85 years who have diagnostic criteria for type 2 diabetes mellitus

Intervention groups

1.Intervention group: Receiving F. assa-foetida capsule
2.Control group: Receiving placebo capsule

Main outcome variables

Fasting blood sugar (FBS) and 2-hours postprandial (2-hpp); Glycated hemoglobin; Serum triglyceride, LDL and total cholesterol levels; Serum HDL levels; Liver enzymes SGOT and SGPT, Serum leptin levels; Inflammation markers hs-CRP, ESR, MDA, AGEs; Activity of antioxidant enzymes SOD, glutathione peroxidase, and serum catalase

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190525043704N1**
Registration date: **2019-09-23, 1398/07/01**
Registration timing: **prospective**

Last update: **2019-09-23, 1398/07/01**
Update count: **0**

Registration date

2019-09-23, 1398/07/01

Registrant information

Name

Mahshid Naghashpour

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-05, 1398/09/14

Expected recruitment end date

2020-03-04, 1398/12/14

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of F. assa-foetida and Placebo on Antihyperglycemic, Antihyperlipidemic, Anti-inflammatory, and Antioxidant Activities in Type 2 Diabetes Mellitus Patients

Public title
Effect of F. assa-foetida in Diabetese
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 25-25 years Male and female patients Completion of diagnostic criteria for type 2 diabetes mellitus The desire to participate in the study with the ability to understand the relevant information and complete the informed consent form
Exclusion criteria:
Use of warfarin and other coumarin substitutes by the patient Use of increasing blood glucose drugs such as antidepressants (triangles), beta-adrenergic blockers, corticosteroids, diazoxide, diuretics, epinephrine, estrogen, glucagon, isoniazid, lithium, phenothiazines, phenytoin, salicylates and triamterene Use of glucose lowering drugs, including acetaminophen, alcohol, anabolysin steroids, gemfibrosil, monoamine oxidase inhibitors, propranolol, tolazamide, and tolbutamide History of uncontrolled hypertension, congestive heart failure and other cardiovascular disease, liver disease, kidney disease, or any metabolic and clinical disorder, except diabetes mellitus Patients with dangerous disease Renal dysfunction (glomerular filtration rate less than 60 ml / min / 1.73 mm3 of surface area) Participants with recent weight loss or weight gain more than 5% of body weight within 3 months People with type 1 diabetes or other chronic diseases such as stroke and cancer that may affect physical activity Pregnant and lactating women People with psychological illnesses Patient with type 2 diabetes under insulin therapy Smoking during the testing period (increasing blood glucose levels) Patients with sickle cell anemia, thalassemia, Chronic renal failure affecting the hemoglobin A1c Any circumstances that, according to the researcher, do not justify the participation of individuals in the study
Age
From **25 years** old to **85 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **66**
Randomization (investigator's opinion)
Randomized
Randomization description
The random allocation of the participants to the intervention and control groups will be done using random allocation software. Then, envelopes prepare according to the number of participants in the study. It will be recorded number one on the first envelope, the second envelope number 2, and etc. In each envelope, the assignment of each individual is determined by the software. In this way, the specified envelope for each individual will be opened and the individual will be assigned to one of the intervention and/or control groups according to the option recorded in the envelope.
Blinding (investigator's opinion)
Double blinded
Blinding description
Participants and researchers will not informed about the assigned group (double blind). The placebo will also be used in the control group to control the effect of induction following the administration of the capsules.
Placebo
Used
Assignment
Parallel
Other design features
This study was designed as a double-blind randomized, placebo-controlled clinical trial. Samples will be selected from an outpatient referral to a private clinic that has been consulted by an internal medicine specialist, Type 2 diabetes mellitus has been approved by the physicin, and have provided the inclusion criteria of the study. Diabetic patients who are willing to participate in the study and complete the consent form will be enrolled in the study.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commiittee of Abadan facukty of medical sciences
Street address
Airport Ave.
City
Abadan
Province
Khouzestan
Postal code
6313833177
Approval date
2019-07-09, 1398/04/18
Ethics committee reference number
IR.ABADANUMS.REC.1398.024

Health conditions studied

1

Description of health condition studied
Type 2 diabetes mellitus
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Fasting blood sugar
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Colorimetric method using spectrophotometer

2

Description
2 hour post prandial
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Colorimetric method using spectrophotometer

3

Description
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Calorimetry with ELISA reader

4

Description
Serum glutathione peroxidase enzyme activity
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Calorimetry with ELISA reader

5

Description
Serum catalase enzyme activity
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Calorimetry with ELISA reader

6

Description
Serum LDL level
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Colorimetric method using spectrophotometer

7

Description
Serum HDL levels
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Colorimetric method using spectrophotometer

8

Description
Serum total cholestrol
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Colorimetric method using spectrophotometer

9

Description
Serum triglyceride levels
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Colorimetric method using spectrophotometer

10

Description
Body weight
Timepoint
At the beginning of the study (before the start of the study), on days 45 and 90 after the start of taking the Asafin capsule
Method of measurement
Scales

11

Description
Waist circumference
Timepoint
At the beginning of the study (before the start of the study), on days 45 and 90 after the start of taking the Asafin capsule
Method of measurement
Meter strip

12

Description
Waist to hip ratio (WHR)
Timepoint
At the beginning of the study (before the start of the study), on days 45 and 90 after the start of taking the Asafin capsule
Method of measurement
Calculate the ratio

13

Description
Body Mass Index (BMI)
Timepoint
At the beginning of the study (before the start of the study), on days 45 and 90 after the start of taking the Asafin capsule
Method of measurement
Calculate the ratio of weight to squared height

14

Description
high-sensitivity C-reactive protein (hs-CRP)
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Calorimetry with ELISA reader

15

Description
erythrocyte sedimentation rate (ESR)
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
erythrocyte sedimentation rate

16

Description
Malondialdehyde(MDA)
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Calorimetry with ELISA reader

17

Description
Advanced glycation end-products (AGEs)
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
ELISA and ELISA reader

18

Description
Serum glutamic oxaloacetic transaminase (SGOT)
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Colorimetric method using spectrophotometer

19

Description
serum glutamic-pyruvic transaminase (SGPT)
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Colorimetric method using spectrophotometer

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Description
Glycated hemoglobin (Hb A1c)
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
Colorimetric method using spectrophotometer

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Description
serum leptin level
Timepoint
At the beginning of the study (before the start of the study) and 90 days after the start of taking the Asafin capsule
Method of measurement
ELISA and ELISA reader

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Receiving F. assa-foetida capsule called Asafin at dose of 250 mg twice daily for 3 mounts. It is necessary to mention that standard treatment is glucose lowering drugs such as glibenclamide and metformin and all subjects should receive standard treatment. Drug formulation: Studies on animal and human species used the plant's resin to determine the effects of the drug. Due to the unpleasantness of this part of the plant for the patient and the likelihood of decreasing the adaptation, according to the drug formulation used in the similar study, 250 mg of the root and seed of the plant in powder form will be used to make Asafin capsule. The drug will be formulated by the Pharmacology Laboratory of the Faculty of Pharmacy, Ahwaz University of Medical Sciences, Ahwaz, Iran.

Category

Treatment - Drugs

2

Description

Control group: Receiving placebo capsule (starch) at a dose of 250 mg twice daily for 3 mounts. It is necessary to mention that standard treatment is glucose lowering drugs such as glibenclamide and metformin and all subjects should receive standard treatment. The placebo will be formulated by the Pharmacology Laboratory of the Faculty of Pharmacy, Ahwaz University of Medical Sciences, Ahwaz, Iran.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

private clinic

Full name of responsible person

Mahshid Naghashpour

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No. 1831, Kasra lane, South Bovardeh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Abadan University of Medical Sciences

Full name of responsible person

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Abadan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Abadan Faculty of Medical Sciences

Full name of responsible person

Mahshid Naghashpour

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Full name of responsible person
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Latest degree
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
As stated in the consent form of the research, the researchers involved in the study kept all information about the patient confidential and are only allowed to publish the general and group results of this research without mentioning their names and specifications. Patients also know that they can have their own personalized results.

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
Data relating to the primary outcome will be shared.

When the data will become available and for how long
Start of access period from 2020

To whom data/document is available
Data will be available to researchers working in academic and scientific institutes.

Under which criteria data/document could be used
Access to data is solely intended to inform investigators and referees of their truthfulness and may not be used elsewhere.

From where data/document is obtainable
If published a paper, data will be available as an supplementary file.

What processes are involved for a request to access data/document
Following the publication of an article extracted from this clinical trial, readers can access data file. If not available, contact the researcher by email in order to provide it as soon as possible.

Comments
The study protocol and its statistical analysis will be available to academic researchers following the article publication. However, only the data obtained from the primary outcome of the intervention will be published as a supplementary file of the published article by deleting the individual information of the patients and considering the roles of research ethics.