Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation the Effect of Oral Aloe Vera Administration on Fasting Plasma Glucose, Lipid Profile, Body Composition Components, Anthropometric Indices, and Blood Pressure Values in Patients with Diabetes Type 2

Protocol summary

Study aim

Determining the effect of consuming aloe vera food powder on fasting blood sugar, lipid profile, body indicators measurement, combination of body mass and blood pressure of patients with type 2 diabetes

Design

Clinical trial with control group, with parallel, double-blind, randomized groups

Settings and conduct

In this randomized clinical trial, double blind study 60 individuals with type 2 diabetes participated. After obtaining the consent of the eligible people to participate in the study, at the beginning and end of the study, after 11 hours of fasting at night, blood samples were collected and demographic information, body measurement and food intake were obtained. The participants were randomly assigned to two intervention groups (aloe vera) and placebo for 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1) The desire to participate in the study 2) Age range 18 to 69 years 3) Diagnosis of type 2 diabetes by a specialist 4) Duration of type 2 diabetes, at least 6 months 5) Having stable weight over the past 6 months(Self-report) 6) The type and dose of drugs used to be stable in the last 6 months Exclusion criteria 1) No Allergy to aloe vera or products containing it 2) No pregnancy and breastfeeding 9) No using any food supplement in the last 6 months 3) No smoking and being addicted 4) NO acute heart disease, stroke, liver, kidney, gastrointestinal, thyroid and parathyroid, rheumatoid and infectious arthritis

Intervention groups

One group was given an oral aloe vera powder and the other group was given an oral tost flour

Main outcome variables

The oral effects of aloe vera on fasting glucose, triglycerides and weight, body mass index, abdominal circumference and systolic blood pressure were investigated in people with type 2 diabetes.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200331046900N1**
Registration date: **2020-06-24, 1399/04/04**
Registration timing: **retrospective**

Last update: **2020-06-24, 1399/04/04**
Update count: **0**

Registration date

2020-06-24, 1399/04/04

Registrant information

Name

Najmeh sadat Zareayan jahromi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 9101 1710

Email address

najmeh.zareayan@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-21, 1397/11/01

Expected recruitment end date

2019-03-19, 1397/12/28

Actual recruitment start date

2019-02-24, 1397/12/05

Actual recruitment end date

2019-03-03, 1397/12/12

Trial completion date

2019-06-09, 1398/03/19

Scientific title

Evaluation the Effect of Oral Aloe Vera Administration on Fasting Plasma Glucose, Lipid Profile, Body Composition Components, Anthropometric Indices, and Blood Pressure Values in Patients with Diabetes Type 2

Public title

Effect of oral aloe vera powder on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The desire to participate in the study Age range 18 to 69 years Diagnosis of type 2 diabetes by a specialist The minimum duration of type 2 diabetes is 6 months Weight constant over the past 6 months (Self-report) The type and dose of medications taken have been stable over the past 6 months

Exclusion criteria:

Allergy to aloe vera or products containing it Pregnancy and lactation Use of any dietary supplement in the last 6 months Smoking and addiction Acute heart disease, stroke, liver, kidney, gastrointestinal, thyroid and parathyroid disease, rheumatoid and infectious arthritis

Age

From **18 years** old to **69 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**
More than 1 sample in each individual
Number of samples in each individual: **2**
Before the intervention and after the intervention
Actual sample size reached: **60**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Before the intervention and after the intervention

Randomization (investigator's opinion)

Randomized

Randomization description

The allocation of participants in two groups of intervention and control is done by the Balanced block randomization method. (Randomization of people between the two groups will be done by blocking method. Thus, the size of the blocks is considered to be 4 and all possible cases are written for groups A and B, and this will be done until the number reaches 60 people.) It is repeated. Then, using a table of random numbers, each of the components of the blocks is given a number. The numbers given to each of the components of the blocks represent the number intended for each person that has already been determined. So the order of the group assigned to each person is specified).

Blinding (investigator's opinion)

Double blinded

Blinding description

Study participants, researchers, and assistants did not know who was in the intervention group and who was in the placebo group. The person who checked the information did not know which group the person belonged to, and the person who delivered the drugs did not know which group was interfering and knew groups 1 and 2. In addition, for weekly follow-ups, the first person was in contact with people who did not know in which group the person was. Participants did not know from the beginning to the end of study which group they were in.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Zand

City

Shiraz

Province

Fars

Postal code

7134814336

Approval date

2019-03-06, 1397/12/15

Ethics committee reference number

IR.SUMS.REC.1398.210

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11.9

ICD-10 code description

Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Total cholesterol

Timepoint

Before the intervention and after the intervention

Method of measurement

Blood test

Secondary outcomes

1

Description

Fasting blood sugar

Timepoint

Before and after the intervention

Method of measurement

Blood test

2

Description

Triglyceride

Timepoint

Before and after the intervention

Method of measurement

Blood test

3

Description

High-density lipoprotein

Timepoint

Before and after the intervention

Method of measurement

Blood test

4

Description

Low-density lipoprotein

Timepoint

Before and after the intervention

Method of measurement

Blood test

5

Description

Anthropometry

Timepoint

Before and after the intervention

Method of measurement

Scales, meters, calipers and ...

6

Description

Blood pressure

Timepoint

Before and after the intervention

Method of measurement

Blood pressure monitor

Intervention groups

1

Description

Intervention group: The raw materials and raw materials required were purchased from Shiraz University of Medical Sciences School of Pharmacy with the advice and approval of a consultant, and then combined under standard conditions and intervened as a supplement. Finally, the capsule contained the main intervention containing 500 mg of aloe vera of the species Barbadensis Aloe prepared by Adonis Gol Daru Company (which was placed in a capsule and patients were advised to take 2 tablets daily for 56 days (1 after breakfast and 1 after dinner).

Category

Treatment - Drugs

2

Description

Control group: 500 mg test powder with the advice and approval of a consultant from Shiraz University of Medical Sciences School of Pharmacy in a capsule that was exactly the same in terms of shape, color, smell and size with the capsule containing the main intervention and as a placebo to participants. It is recommended to take 2 tablets daily for 56 days (1 after breakfast and 1 after dinner).

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Qutbuddin Hospital

Full name of responsible person

Mehdi Ayaz

Street address

Fakhrabad

City

Shiraz

Province

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7163854733

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person
Dr. Mehrzad Lotfi
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7134814336
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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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Najmeh Sadat Zareian Jahromi
Position
Master of Nutrition
Latest degree
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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

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
Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The Excel file contains all the data

When the data will become available and for how long

Start the access period 6 months after printing the results

To whom data/document is available

Data will only be available to researchers working at academic and scientific institutions

Under which criteria data/document could be used

Get permission before using the project executor

From where data/document is obtainable

Dr. Siavash Baba Jafari: jafaris@sums.ac.ir Najmeh Sadat Zareian Jahromi: najmeh.zareayan@gmail.com

What processes are involved for a request to access data/document

The applicant will introduce himself in an email and explain the reason for the need for data. After review, the data will be sent within a week if agreed.

Comments