Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Aloe Vera leaf gel dry powder on blood glucose level in type II diabetic patients, A double – blind, randomized, placebo controlled trial

Protocol summary

Summary

- The present study was designed to investigate the efficacy of Aloe Vera leaf gel dry powder on blood glucose level in type II diabetic patients.108 patients aged between 40 to 60 years, with confirmed type II diabetes (fasting blood glucose above 150-250 mg/dl and HbA1c 7.5-10% taking antidiabetic drug such as Metformin or Glibenclamid that signed the written informed consent will be selected. The patients will continue their standard anti-diabetic therapy without any change during the study. All patients who suffering from severe kidney, liver, heart and pulmonary diseases, hypersensitivity to any drug, foot ulcer or gangrene, depression and previous myocardial infarction, active cancer or previous cancer during the last 5 years, alcoholic or cigarette smoker, pregnant and breast feeding patients will be excluded. The patients will be randomly allocated into one of three groups. Two groups will receive 150 and 300 mg Aloe Vera as capsules, respectively, two times daily and third group will receive placebo capsules which are the same as true drugs. Fasting blood glucose, glycosilated hemoglobin, total cholesterol, LDL, HDL cholesterol, triglyceride, creatinine, SGOT and SGPT will be measured at the beginning and after two months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138706161157N2**
Registration date: **2009-04-13, 1388/01/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2009-04-13, 1388/01/24

Registrant information

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Hasan Fallah Huseini
Name of organization / entity
Institute of Medicinal Plants
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Recruitment status

Recruitment complete

Funding source

Jahad Daneshgahii and Shaheed Seduqi medical college Yazd Yniversity

Expected recruitment start date

2009-04-21, 1388/02/01

Expected recruitment end date

2010-04-22, 1389/02/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Aloe Vera leaf gel dry powder on blood glucose level in type II diabetic patients, A double – blind, randomized, placebo controlled trial

Public title

The effect of Aloe Vera leaf gel dry powder on blood glucose level in type II diabetic patients, A double – blind, randomized, placebo controlled trial

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 40 to 60 years, confirmed

type II diabetes at least for two years with fasting blood glucose above 150-250 mg/dl taking Metformin or Glibenclamid, HbA1c 7.5-10%, singing the written informed consent. Exclusion criteria: insulin therapy, infectious diseases, severe kidney, liver, heart, or pulmonary disease, hypersensitivity to any drug, foot ulcer or gangrene, major depressive disorders, previous myocardial infarction, active cancer or previous cancer during the last 5 years, alcohol consumption, cigarette smoking, pregnancy, and breast feeding.

Age
From **40 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **108**

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
Avicenna Research Institute of Academic Center for Education Culture

Street address
Shaheed Beheshti University, Shaheed Chamran Highway

City
Tehran

Postal code
1177-19615

Approval date
empty

Ethics committee reference number
492/51/29 گ ي

Health conditions studied

1

Description of health condition studied
Diabetes

ICD-10 code
E11

ICD-10 code description
Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
Fasting blood glucose

Timepoint
Baseline and after one and two months

Method of measurement
Glucose oxidase method.

2

Description
Glycosylated hemoglobin

Timepoint
Baseline and after two months

Method of measurement
HPLC method

Secondary outcomes

1

Description
SGOT

Timepoint
Baseline and after two months

Method of measurement
SGOT level in fasting blood sample by DGKG enzymatic method

2

Description
SGPT

Timepoint
Baseline and after two months

Method of measurement
SGPT level in fasting blood sample by DGKG enzymatic method

3

Description
Creatinin

Timepoint
Baseline and after two months

Method of measurement
The fasting blood Creatinin level by JAPH enzymatic method

4

Description
Cholesterol

Timepoint
Baseline and after two months
Method of measurement
Fasting blood Cholesterol level by enzymatic oxidase method.

5

Description
LDL
Timepoint
Baseline and after two months
Method of measurement
Fasting blood LDL level by CDC designated comparison method.

6

Description
HDL
Timepoint
Baseline and after two months
Method of measurement
Fasting blood HDL level by enzymatic oxidase method

7

Description
Triglyceride
Timepoint
Baseline and after two months
Method of measurement
Fasting blood Triglyceride level by enzymatic oxidase method

Intervention groups

1

Description
Aloe vera jell powder 150 mg in capsule two times a day for two months
Category
Treatment - Drugs

2

Description
Aloe vera jell powder 300 mg in capsule two times a day for two months
Category
Treatment - Drugs

3

Description
placebo 150 mg in capsule two times a day for two months
Category
Placebo

4

Description
placebo 300 mg in capsule two times a day for two months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Diabetic Research Center
Full name of responsible person
Dr M. Afkhami
Street address
Afshar Hospital
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Jahad Daneshgahi
Full name of responsible person
Haji Tarverdi
Street address
Jahad Daneshgahi, Enghelab St.
City
Tehran
Grant name
صبر زرد 29-20-25718
Grant code / Reference number
1461-33
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Jahad Daneshgahi
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
Institute of Medicinal Plants, ACECR
Full name of responsible person

Fallah Huseini Hassan

Position
Ph.D.

Other areas of specialty/work

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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