

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Name

Hasan Fallah Huseini

Name of organization / entity

Institute of Medicinal Plants

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Iran (Islamic Republic of)

Phone

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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%, signing 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 ی

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

29-20-25718 صبر زرد

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