

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3476 4010

##### Email address

fallah@imp.ac.ir

#### 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**

**Street address**

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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*