Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Evaluation of the effectiveness of a new herbal formulation for improving blood sugar control in patients with type 2 diabetes mellitus.

Protocol summary

Summary

The aim of the present study is to find a combination herbal formulation of Aloe vera gel and fenugreek seeds for improving symptoms of diabetes type 2. After quality and quantity control of herbal materials and pharmacological study (in vivo), antidibetic effects of the herbal product is evaluated during clinical trial. A total of 60 patients with diagnosed diabetes mellitus type 2 randomly assigned to take either drug or placebo in a double-blind design. For two month, the patients should receive one tablet orally per day. Changes in blood glucose and plasma insulin levels are monitored at the 4th and 8th weeks.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109207602N1**
Registration date: **2015-01-06, 1393/10/16**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-01-06, 1393/10/16

Registrant information

Name

Parisa Sarkhail

Name of organization / entity

Pharmaceutical Sciences Research Center, Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Iran's National Elites Foundation (INEF)

Expected recruitment start date

2014-12-22, 1393/10/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effectiveness of a new herbal formulation for improving blood sugar control in patients with type 2 diabetes mellitus.

Public title

The effect of herbal supplement in type 2 diabetes treatment.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:newly diagnosed diabetes according to ADA 2014 (FPG=>126 mg/dl or HgA1C=>6.4% or BS=>200 mg/dl after OGTT or random BS =>200 and hyperglycemic symptoms); age 30-65 years; signed consent form. Exclusion criteria: Diabetes type 1; insulin injection during 8 weeks ago; serious infectious diseases; renal failure (GFR< 50 cc/min/); liver failure (high ALTor/and AST more than 3 times above normal range); cardiac failure; pregnancy and/or breast feeding; past history of seizure or epilepsy.

Age

From **30 years** old to **65 years** old

Gender

Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **60**
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
Vice- Chancellor for Research,Tehran University of Medical Sciences
Street address
Blv. Keshavarz, Ghods St.
City
Tehran
Postal code
Approval date
2011-10-19, 1390/07/27
Ethics committee reference number
90/130/1305/د

Health conditions studied

1

Description of health condition studied
Diabetes
ICD-10 code
E10-E14
ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Blood Glucose
Timepoint
In the beginning and at the end of 4th and 8th weeks of the trial.
Method of measurement
Blood test

Secondary outcomes

1

Description
Blood insulin
Timepoint
In the beginning and at the end of 4th and 8th weeks of the trial.
Method of measurement
Blood test

2

Description
Cholesterol and triglyceride
Timepoint
In the beginning and at the end of 8th week of the trial.
Method of measurement
Blood test

Intervention groups

1

Description
The placebo will be prescribed one tablet orally per day to the control group for two months.
Category
Treatment - Drugs

2

Description
The herbal formulation will be prescribed one tablet orally per day to the intervention group for two months.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology & Metabolism Research Institute,Tehran University of Medical Sciences
Full name of responsible person
Ensieh Nasli-Esfahani
Street address
Diabetes Research Center, Shahrivar St., North Kargar Avenue,
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran's National Elites Foundation (INEF)

Full name of responsible person

Masood Yonesian

Street address

Pharmaceutical Sciences Research Center, Faculty of Pharmacy, Tehran University of Medical Sciences, 16th Azar St.,

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran's National Elites Foundation (INEF)

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

Pharmaceutical Sciences Research Center

Full name of responsible person

Parisa Sarkhail

Position

Pharm D. and Ph.D in Pharmacognosy/Assistant Prof.

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