

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effects of Diabetan and Saliva officinalis L tablets on blood glucose levels of patients with type 2 DM.

Protocol summary

Summary

Nowadays, people show an increasing interest in using natural products. In this study the effect of Diabetan pill that is a blend of Saliva officinalis, Trigonella foenum and Ginseng will be investigated on blood glucose of diabetic patients. Methods: In a double-blind clinical trial 80 diabetic patients referred to endocrine and metabolism clinic in Shahrekord (Iran) will be selected and randomly designated into two groups of case and control. The case group will receive Diabetan and the control group will receive placebo tablets three times a day for three months. Glycosylated hemoglobin, lipid profile, fasting blood sugar (FBS) and 2 hours postprandial (2hpp) will be measured at the beginning and every 2 weeks, for three months. Hepatic enzymes will also evaluated and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201011112696N2**

Registration date: **2010-12-18, 1389/09/27**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2010-12-18, 1389/09/27

Registrant information

Name

Mahmoud Rafeian-kopaei

Name of organization / entity

Shaharekord University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 38 1334 6692

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rafieian@skums.ac.ir

Recruitment status

Recruitment complete

Funding source

Gol Daru Company

Expected recruitment start date

2010-10-23, 1389/08/01

Expected recruitment end date

2011-02-20, 1389/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of Diabetan and Saliva officinalis L tablets on blood glucose levels of patients with type 2 DM.

Public title

Effects of Diabetan and Saliva officinalis L tablets on blood glucose levels of patients with type 2 DM.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1-Having type 2 diabetes based on internal criteria with FBS=126 or more and blood glucose 200 or more in daytime. 2- HbA1C more than 7% and less than 9% 3-Not having side effects of DM 4-Non-insulin dependent 5-Willing to participate in the trial 6- Not having a crucial illness 7- psychologically normal 8- Not using any other drugs for other diseases. Excluding Criteria: 1- Hyperglycemia with HbA1C more than 250 2-2hpp more than 9% and less than 7% 3-Pregnancy and lactation 4- Using insulin 5- Not willing to enter the trial 6- Having side effects of DM 7- Cardiovascular, hepatic, renal and other major systemic diseases 8-

psychologically abnormal 9- Using drugs for other illnesses 10- Type 1 DM 11- Age less than 30 years

Age

From **30 years** old to **149 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

N/A

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

Ethical committee of Shahrekord University of Medical Sciences

Street address

Shahrekord, kashani St, Shahrekord University of Medical Sciences

City

Shahrekord

Postal code

Approval date

2010-04-11, 1389/01/22

Ethics committee reference number

87-11-2

Health conditions studied

1

Description of health condition studied

Diabetes Melitus (DM)

ICD-10 code

E10, E11,

ICD-10 code description

Diabetes Melitus

Primary outcomes

1

Description

HbA1C

Timepoint

At the beginning and at the end of trial (in 3 months)

Method of measurement

Laboratory mg/ dl

2

Description

Lipid profile

Timepoint

At the beginning and end of the trial (in 3 months)

Method of measurement

mg/dl through lab methods

3

Description

Liver and kidney parameters

Timepoint

At the beginning and end of the trial (in 3 months)

Method of measurement

mg/dl through lab methods

4

Description

FBS and HbA1C

Timepoint

at the beginning of trial and every 2 weeks

Method of measurement

mg/dl

Secondary outcomes

empty

Intervention groups

1

Description

Diabetan tablet will be prescribed for them 3 times per day for three months

Category

Treatment - Drugs

2

Description

Placebo tablet will be prescribed 3 times per day for three months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Metabolism clinic of Shahrekord University of Medical Sciences

Full name of responsible person

Mohamad Saeed Behradmanesh

Street address

Metabolism clinic of Shahrekord University of Medical Sciences

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Specialist

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Gol Daru Co.

Full name of responsible person

Dr Falamarzian

Street address

Isfahan-Sofeh Shahrak-Gol Daru

City

Isfahan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Gol Daru Co.

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**

Shahrekord University of Medical Sciences

Full name of responsible person

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Web page address**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