

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jul 2026

comparsion of the Effects of an anti-diabetic oligosaccharide rich fraction extracted from Rosa arvensis with common treatment on diabetic patients type2(a pilot study)

Protocol summary

Summary

The purpose of this pilot study is assessing the anti-diabetic effects of rich Oligosaccharides fraction which is taken from Rosa arvensis in patients with type 2 diabetes. This study is a double blind clinical trial. 40 diabetic patients (type 2) referring to the Diabetes Research Center were randomly divided into two intervention and control groups. The intervention group receive three capsules daily, each containing 350 mg of rich Oligosaccharides fraction taken from Rosa arvensis which is added to the standard treatment and in case of decreasing blood sugar and improvement, other drugs are gradually discontinued and after three months of normal blood glucose, rich Oligosaccharides fraction dose is gradually reduced to three days a week, 700 mg daily. In the control group, treatment with a common protocol continues. Then at baseline, 3 and 6 months later, blood sugar (FBS), glucose tolerance test (BS) and Hba1c are compared in both groups. Inclusion criteria: diabetes diagnosis with fasting blood sugar over 125, or postprandial glucose over 200 or glycosylated hemoglobin level greater than 6; patient willingness and signed informed consent, age less than 65 years; history of diabetes less than 10 years; diabetes onset at least three months before. Exclusion criteria: requiring insulin injections or diagnosis of type 1 diabetes, kidney disease, liver disease, cancer, anemia and heart failure, pregnancy, glycosylated hemoglobin over 10, corticosteroids use.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013120214333N13**

Registration date: **2013-12-24, 1392/10/03**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-12-24, 1392/10/03

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

froughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-03-20, 1392/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparsion of the Effects of an anti-diabetic oligosaccharide rich fraction extracted from Rosa arvensis with common treatment on diabetic patients type2(a pilot study)

Public title

A Pilot study of anti-diabetic effects of rich Oligosaccharides fraction which is taken from Rosa arvensis in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: diabetes diagnosis with fasting blood sugar over 125, or postprandial glucose over 200 or glycosylated hemoglobin level greater than 6; patient willingness and signed informed consent, age less than 65 years; history of diabetes less than 10 years; diabetes onset at least three months before. Exclusion criteria: requiring insulin injections or diagnosis of type 1 diabetes, kidney disease, liver disease, cancer, anemia and heart failure, pregnancy, glycosylated hemoglobin over 10, corticosteroids use.

Age

From **1 year** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences
Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

City

Kermanshah

Postal code

Approval date

2013-09-11, 1392/06/20

Ethics committee reference number

7/420/24151/پ

Health conditions studied

1

Description of health condition studied

diabetes of type2

ICD-10 code

E11

ICD-10 code description

Non-insulin dependent diabetes mellitus

Primary outcomes

1

Description

blood sugar (FBS)

Timepoint

Baseline, 3 and 6 months after starting the study

Method of measurement

Test

2

Description

glucose tolerance test (BS)

Timepoint

Baseline, 3 and 6 months after starting the study

Method of measurement

Test

3

Description

Hba1c rate

Timepoint

Baseline, 3 and 6 months after starting the study

Method of measurement

Test

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group receive three capsules daily, each containing 350 mg of rich Oligosaccharides fraction taken from Rosa arvensis which is added to the standard treatment and in case of decreasing blood sugar and improvement, other drugs are gradually discontinued and after three months of normal blood glucose, rich Oligosaccharides fraction dose is gradually reduced to three days a week, 700 mg daily

Category

Treatment - Drugs

2

Description

Control group receive treatment with a common protocol.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabets Research Center

Full name of responsible person

Dr. Mehrali Rahimi

Street address

Diabets Research Center,Taleghani Hospital,Shahid Beheshti Boulevard

City

Kermanshah

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Barekat Pharmaceutical Company

Full name of responsible person

Dr. Hamidreza Jamshidi

Street address

Barekat Pharmaceutical Company,Fifth Street,khaled Estamboli street,Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Barekat Pharmaceutical Company

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

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Bahrani

Position

Pharmacologist

Other areas of specialty/work

Street address

Medical Biology Research Center,Prastar Boulevard,Sorkhleje

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Postal code

Phone

+98 83 1427 6471

Fax

Email

gbahrani@kums.ac.ir

Web page address

Person responsible for updating data

Contact

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