Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)
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+98 83 1821 4653
Email address
fforoughi@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 SciencesBuilding 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 Bahrami
Position
Pharmacologist
Other areas of specialty/work
Street address
Medical Biology Research Center,Prastar Boulevard,Sorkhleje
City
Kermanshah
Postal code
Phone
+98 83 1427 6471
Fax
Email
gbahrami@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