Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of Ribes khorassanicum hydro ethanolic extract supplementation compared with placebo on metabolic parameters of diabetes in type 2 diabetic patients

Protocol summary

Summary

The purpose of this study is to evaluate the effect of Ribes khorassanicum hydro ethanolic extract supplementation on metabolic parameters of type 2 diabetic patients. The study design is randomized, double blind (both patients and researchers) placebo controlled trial. The study population consists of type 2 diabetes patients (aged 35–60 years) presenting to Diabetes clinic (Emam Reza Hospital, Mashhad University of Medical Sciences). One hundred eligible patients will be chosen and assigned to intervention and placebo groups by random allocation (Permuted block randomization). Patients with 6 months diagnosed diabetes and treated with anti-diabetic drug will be included. Patients with cardiac, renal, hepatic diseases and who had concomitant infections, insulin injection, smoking, pregnancy and breastfeeding, recent (in the last month) and concurrent use of herbal medications, aspirin and anticoagulant drug will be excluded. The patients will be treated with Ribes khorassanicum hydro ethanolic extract (1 capsule=500 mg, every 12 h) or placebo for 3 months. Before and at the end of the study, patients' blood samples will be taken and fasting blood sugar, 2-h post-prandial, glycated hemoglobin, fasting insulin, fasting blood levels of lipids, liver enzymes and creatinine will be measured. Body mass index, diastolic and systolic pressure will be evaluated too.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030432857N1**
Registration date: **2017-04-27, 1396/02/07**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-04-27, 1396/02/07

Registrant information

Name
Zahra Gholamnezhad
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2017-08-22, 1396/05/31

Expected recruitment end date

2018-09-21, 1397/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Ribes khorassanicum hydro ethanolic extract supplementation compared with placebo on metabolic parameters of diabetes in type 2 diabetic patients

Public title

The effect of Ribes khorassanicum in diabetes treatment

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 35-60, with 6 month diagnosed diabetes (FBS≥126 mg/dL, Blood sugar, 2-h post-prandial ≥ 200 mg/dL and HbA1c ≥ 6.5) and used anti-diabetic drug. Exclusion criteria: Patients with cardiac, renal, and hepatic diseases, patients who had concomitant infections, insulin injection, smoking, pregnancy and breast-feeding, patients with recent (in the last month) and concurrent use of herbal medications, aspirin, anticoagulant drug and any report of probable side effect of this study intervention.

Age

From **35 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

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

Ethics committee of Mashhad University of Medical Sciences

Street address

Vice chancellor for research, Ghoraishy Building, University Street, Mashhad

City

Mashhad

Postal code

Approval date

2017-02-08, 1395/11/20

Ethics committee reference number

IR.MUMS.fm.REC.1395.544

Health conditions studied

1

Description of health condition studied

type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description

FBS

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Enzymatic kit

2

Description

2-h post-prandial

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Enzymatic kit

3

Description

HbA1c

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Enzymatic kit

4

Description

Fasting insulin

Timepoint

Before intervention, 3 month after intervention

Method of measurement

ELISA kit

Secondary outcomes

1

Description

Hepatic Enzymes

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Enzymatic kit

2

Description

Creatinine

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Enzymatic kit

3

Description

Fasting blood levels of lipids

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Enzymatic kit

4

Description

Body mass index

Timepoint

Before intervention, 3 month after intervention

Method of measurement

height (cm), weight (kg), BMI (kg/square meters)

5

Description

Blood pressure

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Sphygmomanometer

Intervention groups

1

Description

Intervention group: patients will be treated with Ribes khorassanicum hydro ethanolic extract (1 capsule = 500 mg, every 12 h) for 3 months.

Category

Treatment - Drugs

2

Description

Placebo group: patients will be treated with placebo (1 capsule = 500 mg, every 12 h) for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Masoud Mohebbi

Street address

Emam Reza Hospital, Emam Reza Square, Ebne Sina Avenue, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

Street address

Vice chancellor for research of Mashhad University of Medical Sciences, Ghoraishy Building, University Street, Mashhad

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Zahra Gholamnezhad

Position

PhD of physiology, Assistant Professor

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