

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of *Berberis integerrima* fruit extract on the indicators of glycemic control in type 2 diabetic patients: A Randomized Controlled Clinical Trial

Protocol summary

Study aim

To evaluate the efficacy of Barberry extract on blood glucose control indices in patients with type 2 diabetes

Design

A Randomized controlled clinical trial. All 60 people who meet the inclusion criteria of present Randomized Controlled Clinical Trial will be randomly divided into intervention and control groups. Block Randomization will be used for randomization. Before entering the study, the study procedure will be fully explained to the individual and a consent form will be provided.

Settings and conduct

In present study, patients will be selected from those referring to Endocrinology and Metabolism Research Center of Isfahan University of Medical Sciences (Sedigheh Tahereh Research Center).

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age between 18 and 80 years; Diagnosis of type 2 diabetes according to ADA criteria with disease duration of at least 2 years; Taking metformin; Glycosylated hemoglobin between 6.5% and 9%. Non-inclusion criteria: Use of alcohol or other substances could be abused: Hepatic or renal disorder; Use of oral antidiabetic drugs increasing insulin secretion (sulfonylureas and repaglinide) and insulin products; pregnancy and lactation.

Intervention groups

Intervention group: Barberry syrup, 5 CC, twice daily for 2 months in addition to self medication. Control group: Patient control for 2 months and following the patient's previous medication regimen.

Main outcome variables

Fasting Blood Glucose; Glycosylated Hemoglobin (HbA1c); Serum Insulin; HOMA-IR.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150721023282N5**

Registration date: **2019-12-13, 1398/09/22**

Registration timing: **retrospective**

Last update: **2019-12-13, 1398/09/22**

Update count: **0**

Registration date

2019-12-13, 1398/09/22

Registrant information

Name

Rasool Soltani

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 3792 7067

Email address

soltani@pharm.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-05-21, 1398/02/31

Expected recruitment end date

2019-10-21, 1398/07/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Berberis integerrima fruit extract on the indicators of glycemic control in type 2 diabetic patients: A Randomized Controlled Clinical Trial

Public title

The effects of Berberis integerrima fruit extract on blood glucose

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age between 18 and 80 years old
Diagnosis of type 2 diabetes according to ADA criteria with disease duration of at least 2 years
Treatment with Metformin

Glycosylated hemoglobin (HbA1c) between 6.5 and 11%

Exclusion criteria:

Using alcohol and other substances which can be abused
Hepatic or renal disorder
Use of oral antidiabetic drugs increasing insulin secretion (sulfonylureas and repaglinide) and insulin products
Pregnancy and lactation

Age

From **18 years** old to **80 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

Block randomization: blocks of size 4 will be used, so that patients will be assigned to drug and control groups based on the determined sequence by the blocks.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Sciences

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Azadi square

City

Esfahan

Province

Isfahan

Postal code

8174673461

Approval date

2019-05-14, 1398/02/24

Ethics committee reference number

IR.MUI.RESEARCH.REC.1398.104

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting Blood Glucose

Timepoint

Before and After Intervention

Method of measurement

Laboratory Test

2

Description

Serum Insulin

Timepoint

Before and After Intervention

Method of measurement

Laboratory Test

3

Description

HbA1C

Timepoint

Before and After Intervention

Method of measurement

HPLC test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Berberis oral solution, 5 ml twice daily, for 8 weeks

Category

Treatment - Drugs

2

Description

Control group: without use of Berberis oral solution, monitoring will be done for 8 weeks.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine and Metabolism Research Center, Isfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Street address

Khorrām street , Jomhourī Eslāmī square

City

Esfahan

Province

Isfahan

Postal code

8187698191

Phone

+98 31 3792 7067

Email

soltani@pharm.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Street address

Isfahan University of Medical Sciences, Hezar Jarib street, Azadi square

City

Esfahan

Province

Isfahan

Postal code

81746-83461

Phone

+98 31 3786 5537

Email

soltani@pharm.mui.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Esfahan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

No 20, Baq̄e Daryache street

City

Esfahan

Province

Isfahan

Postal code

8176776161

Phone

+98 31 3786 5537

Email

soltani@pharm.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Soltani

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Medical Pharmacy

Street address

No 20, Baq̄e Daryache street

City

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8176776161

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+98 31 3786 5537

Email

soltani@pharm.mui.ac.ir

Postal code

8176776161

Phone

+98 31 3792 7067

Email

soltani@pharm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Rasool Slotani

Position

Associate Professor

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Other areas of specialty/work

Medical Pharmacy

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Esfahan

Province

Isfahan

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Confidential protection of patient data

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available