# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 Nov 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 cab 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**
Isfehan

**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 diabet melitus

**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**

Khorram street , Jomhouri Eslami square

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**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

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## Person responsible for scientific inquiries

**Contact**

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Esfahan University of Medical Sciences

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**Position**

Associate Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**
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## 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