

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Investigating the effect of *Berberis integerrima* Bunge extract on blood sugar control in patients with diabetes type2: A clinical trial

Protocol summary

Study aim

Determining the effectiveness of consuming mountain barberry extract on blood sugar control in patients with type 2 diabetes

Design

This study is designed as a randomized, double-blind, placebo-controlled clinical trial. The sample size is 50 people. Randomization in this study will be performed at the individual level using a block randomization method with an allocation ratio of 1:1.

Settings and conduct

This trial will be conducted at the specialized clinic of Imam Reza Hospital in Bojnord on 50 patients with type 2 diabetes. Participants will be randomly allocated to intervention and control groups and will receive mountain barberry extract or a matching placebo for 8 weeks. Fasting blood glucose and glycated hemoglobin will be measured at baseline and at the end of week 8. The study will be double-blind; participants and outcome assessors will be unaware of group allocation, and the study products will be provided in identical, coded packaging.

Participants/Inclusion and exclusion criteria

Inclusion criteria:** Age 30–75 years; confirmed diagnosis of type 2 diabetes; HbA1c between 6.5% and 9%; stable antidiabetic treatment for at least 3 months; willingness to participate in the study. Exclusion criteria:** Severe renal failure; significant liver dysfunction; unstable cardiovascular disease; pregnancy or lactation; concomitant use of antidiabetic herbal supplements; known allergy to barberry; significant changes in blood glucose during the study; occurrence of serious adverse events; withdrawal of consent or failure to continue participation.

Intervention groups

The intervention group will receive 1500 mg/day of standardized mountain barberry extract in two divided doses for 8 weeks. The control group will receive a matching placebo for the same period.

Main outcome variables

Fasting blood glucose; glycated hemoglobin.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260104068538N1**

Registration date: **2026-09-06, 1405/06/15**

Registration timing: **registered_while_recruiting**

Last update: **2026-09-06, 1405/06/15**

Update count: **0**

Registration date

2026-09-06, 1405/06/15

Registrant information

Name

Amirhosein Ramezani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 58 3151 0000

Email address

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-06, 1405/06/15

Expected recruitment end date

2026-10-23, 1405/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Berberis integerrima Bunge extract on blood sugar control in patients with diabetes type2: A clinical trial

Public title

Investigating the effect of Berberis integerrima Bunge extract on blood sugar control in patients with diabetes type 2

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 30 and 65 years Diagnosis of type 2 diabetes mellitus by a physician HbA1c between 7% and 10% at enrollment Stable type and dose of antidiabetic medications for at least three months before enrollment Willingness to participate in the study and provide written informed consent Ability to regularly use the study product during the eight-week intervention period

Exclusion criteria:

Severe renal impairment Severe liver disease Unstable cardiovascular disease Pregnancy or breastfeeding Concurrent use of herbal supplements or products with glucose-lowering effects Known allergy to barberry or barberry-containing products Presence of a disease or condition that interferes with the measurement or interpretation of HbA1c

Age

From **30 years** old to **75 years** old

Gender

Both

Phase

0

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization in this study will be performed at the individual level using block randomization with a 1:1 allocation ratio. To maintain balance between the intervention and control groups, variable block sizes of 4 and 6 will be used. The random allocation sequence will be generated before participant enrollment using computer-generated random numbers by an independent person who is not involved in participant recruitment, assessment, or follow-up. After confirming each participant's eligibility and obtaining informed consent, a unique study code will be assigned according to the order of enrollment. Group allocation will then be performed according to the pre-generated random sequence. For allocation concealment, group assignments will be placed in sequentially numbered,

opaque, light-impermeable, sealed envelopes. The envelopes will be opened in numerical order only after the participant has been formally enrolled and baseline information has been recorded. The person responsible for generating the random sequence and preparing the allocation codes will have no role in participant recruitment, outcome assessment, or data analysis. As the study is double-blind, the mountain barberry extract and placebo will be made similar in appearance, capsule form, packaging, and administration schedule, and will be identified only by study codes. Therefore, both participants and outcome assessors will remain unaware of the assigned intervention.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is designed as a randomized double-blind clinical trial. After obtaining written informed consent and confirming eligibility, participants will be randomly allocated into either the intervention group or the control group using a random number table. Participants in the intervention group will receive the investigational drug, while those in the control group will receive the standard routine treatment according to the approved therapeutic protocol. To ensure proper blinding, the investigational drug and the routine medication will be matched in appearance, color, size, packaging, and administration schedule, and will be provided in coded containers.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of North Khorasan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, North Khorasan University of Medical Sciences, Shahriar St.

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Bojnord

Province

North Khorasan

Postal code

9414974877

Approval date

2025-09-14, 1404/06/23

Ethics committee reference number

IR.NKUMS.REC.1404.084

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Blood sugar control in patients with type 2 diabetes

Timepoint

Fasting blood glucose will be measured at baseline, before the intervention, and at the end of the eighth week after initiation of the intervention.

Method of measurement

Blood sugar will be measured in the laboratory of Imam Reza Hospital (AS) and will be checked after an 8-hour fast.

2

Description

Blood sugar control in patients with type 2 diabetes

Timepoint

Glycated hemoglobin will be measured at baseline, before the intervention, and at the end of the eighth week after initiation of the intervention.

Method of measurement

Blood sugar will be measured in the laboratory of Imam Reza Hospital (AS) and will be checked after an 8-hour fast.

Secondary outcomes

1

Description

HbA1c

Timepoint

The beginning and end of the study

Method of measurement

Laboratory test

2

Description

FBS

Timepoint

The beginning and end of the study

Method of measurement

Laboratory test

3

Description

Consumption of barberry

Timepoint

daily

Method of measurement

Counting of pills taken by the presenter as well as the individual's self-declaration

Intervention groups

1

Description

Intervention group: Participants will receive 1500 mg/day of standardized Berberis integerrima Bunge fruit extract orally for eight weeks. The daily dose will be administered in two divided doses of 750 mg each. The berberine content of the extract will be determined and documented after standardization of the study product. The capsules will be prepared and packaged by [manufacturer/production center]. Participants will continue their usual antidiabetic treatment during the study, and any clinically necessary treatment changes will be documented.

Category

Treatment - Drugs

2

Description

Control group: The control group receives an identical placebo; the placebos are standardized in appearance and packaging to maintain complete blinding.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital (AS) and government clinics in Bojnourd

Full name of responsible person

Amirhosein Ramezani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bojnourd 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

Bojnourd 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**

Bojnourd University of Medical Sciences

Full name of responsible person

Amirhosein Ramezani

Position

Nurse

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Full name of responsible person

Dr.Amir Amani

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Specialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Presentation of research project documentation
investigating the effect of consuming mountain barberry
extract (a plant from the *Berberis integerrima* Bunge

family) on blood sugar control in patients with type 2 diabetes: a clinical trial regarding the study process and participation of individuals in the study, along with submitting the results.

When the data will become available and for how long

Documentation will be uploaded within 1 to 4 months after the article is completed.

To whom data/document is available

Researcher, Supervisor, Analyst

Under which criteria data/document could be used

The use of the data is solely for the purpose of printing and publishing this article. Use in other cases must be possible only with the coordination of the organizer.

From where data/document is obtainable

project manager

What processes are involved for a request to access data/document

Send request by email
ramezani80amirhosein@yahoo.com

Comments