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
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Iran (Islamic Republic of)
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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.

City
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
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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
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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