Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of the Antidiabetic Effect of Dietary Supplement(Denazh supplement) Prepared from Oat and Terminalia chebula fruit in Patients with Prediabetes Type 2 Diabetes: A Single-Blind Clinical Trial

Protocol summary

Study aim

The aim of this study is to compare the effects of Terminalia chebula extract and Terminalia chebula powder combined with oat powder versus placebo on glycemic control indices and lipid profile in individuals with prediabetes.

Design

This study is a randomized, placebo-controlled, three-arm, parallel-group, single-blind clinical trial conducted among 75 participants with prediabetes typ 2

Settings and conduct

This randomized, placebo-controlled, three-arm, parallel, single-blind clinical trial will be conducted among 75 individuals with prediabetes at the 501 Army Hospital in Tehran. Participants will be randomly assigned to receive placebo, black myrobalan (Terminalia chebula) powder, or black myrobalan extract, with the latter two formulations combined with oat powder. They will consume one 6-g sachet daily for 6 weeks. Blood glucose and lipid profiles will be assessed before and after the intervention.

Participants/Inclusion and exclusion criteria

Diagnosis of type 2 prediabetes prior to enrollment in the study Fasting blood glucose greater than 100 and less than 125 Age between 18 and 70 years Willingness to participate in the study and signing of the informed consent form

Intervention groups

Control group (placebo): Participants receive one 6-g sachet of a placebo daily, matched in appearance and taste, with minimal potential effects on glycemic and lipid parameters. Intervention group 1: Participants receive one 6-g sachet daily containing Terminalia chebula powder and oat powder. Intervention group 2: Participants receive one 6-g sachet daily containing Terminalia chebula extract and oat powder.

Main outcome variables

Primary outcomes The primary outcomes of the study were: Fasting blood sugar (FBS) Fasting insulin Insulin resistance index (HOMA-IR) The insulin resistance index was calculated based on fasting blood sugar and fasting insulin values.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260822070751N1**
Registration date: **2026-08-31, 1405/06/09**
Registration timing: **retrospective**

Last update: **2026-08-31, 1405/06/09**
Update count: **0**

Registration date

2026-08-31, 1405/06/09

Registrant information

Name

Vahid Joneirani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-07-23, 1405/05/01

Expected recruitment end date

2026-08-01, 1405/05/10

Actual recruitment start date
2026-07-23, 1405/05/01
Actual recruitment end date
2026-08-01, 1405/05/10
Trial completion date
2026-09-06, 1405/06/15

Scientific title
Evaluation of the Antidiabetic Effect of Dietary Supplement(Denazh supplement) Prepared from Oat and Terminalia chebula fruit in Patients with Prediabetes Type 2 Diabetes: A Single-Blind Clinical Trial

Public title
Evaluation of the Antidiabetic Effect of Dietary Supplement(Denazh supplement) Prepared from Oat and Terminalia chebula fruit in Patients with Prediabetes Type 2 Diabetes: A Single-Blind Clinical Trial
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Fasting blood sugar between 100 and 125 Diagnosis of type 2 prediabetes prior to study entry
Exclusion criteria:
Suffering from a severe acute or chronic illness Need to use diabetes control medications Known allergy to medicinal herbs, black myrobalan (Terminalia chebula), or oats The volunteer's decision to withdraw from the study
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **75**
Actual sample size reached: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: In this study, randomization will be performed individually using block randomization to ensure that the number of participants in each group remains as balanced as possible throughout the allocation process. Statistical software will be used to generate the random sequence. If necessary, blocks of variable sizes may be used to reduce the predictability of allocation. Unit of randomization: The unit of randomization is the individual participant. Stratification variables: Stratified randomization will not be used in this study. Randomization tool: The random sequence will be generated using statistical software, and participants will be allocated to groups based on this sequence. Method of generating the random sequence: A pre-specified random sequence will be generated by an individual independent of the study implementation team. This sequence will be designed based on random blocks and will be used sequentially to allocate participants to the study groups. Allocation concealment: To prevent allocation bias, the random sequence and group allocation information will be concealed from researchers and assessors until the participant enters the study and completes the registration process. Final allocation will be performed by an independent individual using an appropriate allocation concealment methodent: To prevent allocation bias, the random sequence and group assignments will be kept concealed from researchers and assessors until the participant enters the study and the registration process is completed. Final allocation will be performed by an independent person using an appropriate concealment method.
Blinding (investigator's opinion)
Single blinded
Blinding description
Description of study blinding: This study has been designed as a single-blind study. In order to comply with the principles of medical ethics, all participants will be fully informed about the nature of the study, the research process, and its purpose before entering the study, and will sign a written informed consent form. Blinding is limited to concealing the type of intervention (black myrobalan, black seed, or placebo) from the participants. Details of the blinding status of individuals are as follows: Participants: Participants will be unaware of their allocation to the intervention groups (black myrobalan, black seed, or placebo), and the supplements will be prepared to be similar in appearance, color, odor, and packaging. However, participants will be fully aware of the general nature of the study and that they are receiving either a type of herbal supplement or a placebo. Principal investigator and research team: The principal investigator, healthcare personnel, and those responsible for implementing the study will be aware of group allocations in order to monitor patient safety and manage potential adverse events.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Research Ethics Committee of AJA University of Medical Sciences
Street address
Army University of Medical Sciences, Shahid Etemadzadeh St., West Fatemi St., Tehran
City
Tehran
Province

Tehran

Postal code

۱۴۱۱۷۱۸۵۴۱

Approval date

2026-07-20, 1405/04/29

Ethics committee reference number

IR.AJAUMS.REC.1405.075

Health conditions studied

1

Description of health condition studied

Prediabetes type2

ICD-10 code

R73.03

ICD-10 code description

Prediabetes, prediabetic type2

Primary outcomes

1

Description

Fasting Blood Sugar (FBS)

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

Fasting blood sugar (FBS), measured after at least 10–12 hours of fasting from a venous blood sample using an enzymatic glucose oxidase method, expressed in mg/dL, at two time points: study initiation (baseline) and the end of week 6. Changes in this variable relative to baseline constitute the primary outcome of the study.

2

Description

Fasting Insulin

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

Fasting insulin is measured from venous blood samples obtained after 10–12 hours of fasting, using a commercial ELISA kit, and is expressed in µIU/mL.

3

Description

Insulin Resistance

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

The Homeostatic Model Assessment of Insulin Resistance (HOMA-IR) is calculated indirectly using the standard formula: fasting blood glucose (mg/dL) × fasting insulin (µIU/mL) / 405, at baseline and at the end of week 6.

Secondary outcomes

1

Description

Glycated Hemoglobin (HbA1c)

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

Immunoturbidimetry. The principle of this method is that a specific antibody binds to HbA1c, forming an immune complex; the turbidity produced is then measured using a biochemistry autoanalyzer.

2

Description

Low-Density Lipoprotein Cholesterol (LDL-C)

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

LDL-C and HDL-C are measured by direct homogeneous enzymatic method from fasting serum using an automated biochemistry analyzer and reported in mg/dL

3

Description

High-Density Lipoprotein Cholesterol (HDL-C)

Timepoint

Before the start of the intervention and at the end of the intervention

Method of measurement

LDL-C and HDL-C are measured by direct homogeneous enzymatic method from fasting serum using an automated biochemistry analyzer and reported in mg/dL

Intervention groups

1

Description

Control group: Participants will receive one 6-g sachet of a placebo daily, matched in appearance and taste to the intervention products. The placebo sachet contains maltodextrin and will be taken orally once daily

Category

Placebo

2

Description

First intervention group: Participants will receive one 6-g sachet daily containing Terminalia chebula (black myrobalan) powder combined with oat powder. The intervention will be administered orally once daily for 6 weeks.

Category

Treatment - Drugs

3

Description
Second intervention group: Participants will receive one 6-g sachet daily containing Terminalia chebula extract combined with oat powder. The intervention will be administered orally once daily for 6 weeks.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospital501, Islamic Republic of Iran Army
Full name of responsible person
Vahid Hadi
Street address
Army Hospital No. 501, located on E'temadzadeh Street, above the Pakistan Embassy, West Fatemi Street, Tehran, Iran
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vahidhadi1@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Artesh University of Medical Sciences
Full name of responsible person
Said Hadi
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Shahid E'temadzadeh Street, West Fatemi Street, Tehran, Iran
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Postal code
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Phone
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jps.ajaum@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Artesh University of Medical Sciences
Proportion provided by this source
50
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

2

Sponsor
Name of organization / entity
Nazhvan Darou Dena Co
Full name of responsible person
Hamidomid Joneirani
Street address
Tadbir Boulevard, Airport Industrial Town, Yasuj, Iran
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INFO6513@GMAIL.COM
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Nazhvan Darou Dena Co
Proportion provided by this source
25
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

3

Sponsor
Name of organization / entity
Islamic Azad University, Shahreza Branch (IAU Shahreza)
Full name of responsible person
Farzad Ahmadian
Street address
Pasdaran Boulevard, Shahreza, Isfahan, Iran

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Province
Isfehan
Postal code
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Phone
+98 31 5329 2255
Email
JNR.VAHID@GMAIL.COM
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University, Shahreza Branch (IAU Shahreza)
Proportion provided by this source
25
Public or private sector
Private
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
Artesh University of Medical Sciences
Full name of responsible person
Vahid Hadi
Position
Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available