Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

The effect of a traditional Iranian medicine product (fenugreek + black cumin + sumac + comfrey) on the control of blood sugar indicators in patients with type II diabetes compared to the placebo group

Protocol summary

Study aim

evaluate the effect of traditional-Iranian medicine (fenugreek + black cumin + sumac + comfrey) on blood sugar control in patients with type 2 diabetes.

Design

Clinical trial with a placebo group, with parallel groups, triple-blind, in 72 patients, randomized, stratified randomization based on BMI,

Settings and conduct

In this study, 72 patients with type 2 diabetes will be randomly assigned to two groups of 36. The intervention group will receive black seed, fenugreek seeds, sumac, and purslane, and the placebo group will receive capsules containing Oisel for 8 weeks. For the two groups with diabetes, the tests will be conducted in two stages, once at baseline and the second time after 8 weeks.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Use of oral hypoglycemic drugs (not insulin) Use of fixed doses of oral hypoglycemic drugs for at least the past 3 months No nutrition through enteral and parenteral No pregnancy and breastfeeding Individuals with a body mass index above 18.5 No kidney, liver, cardiovascular, thyroid and cancer disease Exclusion criteria: Allergy to the plants studied Following a special diet or taking the supplements Oral contraceptive pill

Intervention groups

In this study, 72 patients with type 2 diabetes were randomly selected and placed in two groups of 36 people randomly. The intervention group, in addition to common diabetes treatments, received 6 capsules daily containing 4 black seeds 2, fenugreek seeds 2, sumac 1, and purslane 1 in an amount of 500 mg, and the placebo group, in addition to common diabetes treatments, received 6 capsules daily containing 500 mg of Ovisel for 8 weeks.

Main outcome variables

Blood sugar indicators; blood lipids; liver enzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141027019705N5**
Registration date: **2025-02-18, 1403/11/30**
Registration timing: **prospective**

Last update: **2025-02-18, 1403/11/30**
Update count: **0**

Registration date

2025-02-18, 1403/11/30

Registrant information

Name

Mehdi Salehi

Name of organization / entity

Tehran University of Medical Sciences

Country

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Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-04-04, 1404/01/15

Expected recruitment end date

2026-03-11, 1404/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of a traditional Iranian medicine product (fenugreek + black cumin + sumac + comfrey) on the control of blood sugar indicators in patients with type II diabetes compared to the placebo group

Public title

Investigation of traditional-Iranian medicine(Nigella sativa , Trigonella foenum- graecum, Rhus coriaria , Portulaca oleracea) products on blood sugar in type II diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes FBS 2- Fasting blood sugar equal to or higher than 126 mg to 200 mg per deciliter or random sugar equal to or higher than 180 mg per deciliter HgbA1c: 6.5 to 9 - Use of oral hypoglycemic drugs (no insulin) No use of sulfonylurea drugs: Amaryl (Glimipride), Donil (Glibenclamide), Diamicron (Gilclazide), Minodiab (Glipizide), Tolbutamide, Tolazamide and glucocorticoids (Glipizide) Gilbenes Taking a fixed dose of oral hypoglycemic drugs for at least the past 3 months Not receiving enteral or parenteral nutrition Not pregnant or breastfeeding Individuals with a body mass index above 18.5 Not having kidney, liver, cardiovascular, thyroid or cancer disease aged 20 to 65 years old

Exclusion criteria:

Having a specific disease that could interfere with the study process Allergy to the plants studied Following a special diet or taking supplements Using Oral contraceptive pill

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

People with type 2 diabetes are divided equally into two intervention and control groups. By stratified randomization based on BMI (between 20 and 25, between 25 and 30, and greater than or equal to 30), people are placed in two intervention and control groups. People are matched between the intervention and control groups based on BMI.

Blinding (investigator's opinion)

Triple blinded

Blinding description

First, the participants are informed about the study. This study is a triple-blind study. The two groups, the drug and the placebo, are given identical capsules. And they are unaware of the contents of the capsules. In addition, the investigator, the analysis unit and/or the DSMB (Data and Safety Monitoring Board) are unaware of the type of intervention they are assigned to.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Research Ethics Committee of Arak University of Medical Sciences, Arak, Iran

Street address

e of Arak University of Medical Sciences, Arak, Iran

City

Arak

Province

Markazi

Postal code

8154794641

Approval date

2024-12-01, 1403/09/11

Ethics committee reference number

IR.ARAKMU.REC.1403.261

Health conditions studied

1

Description of health condition studied

Diabetes type 2

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

fasting blood glucose

Timepoint

Before the intervention begins and at the beginning of

the study, all subjects will have their blood sugar levels measured. After 8 weeks of administering the intervention, all subjects will be retested using the same method and at the same initial location, and the results will be compared.

Method of measurement

Fasting blood sugar is measured by enzymatic colorimetric method. Fasting insulin is measured by enzyme immunoassay method. The QUIKI index is used to calculate insulin sensitivity. To calculate the QUIKI index, fasting insulin is used in U/mlμ scale and fasting glucose is used in mg/dl scale: QUIKI = 1 / [log (FI) + log (FG)] To calculate insulin resistance, the HOMA-IR index is used. To calculate the HOMA-IR index, fasting insulin is used in U/lμ scale and fasting glucose is used in /l nmol scale: HOMA-IR = fasting insulin (μU/L) x fasting glucose (nmol/L)/22.5

2

Description

lipid profile

Timepoint

Before the intervention begins and at the beginning of the study, all individuals will be examined for their lipid profile, and after 8 weeks of administering the desired intervention, all individuals will be retested using the same method and at the same initial location for the second phase of testing, and the results will be compared.

Method of measurement

Serum cholesterol, LDL, HDL, TG are measured by colorimetric enzymatic method.

3

Description

liver enzume

Timepoint

Before the intervention begins and at the beginning of the study, all subjects' liver enzymes will be measured, and after 8 weeks of administering the desired intervention, all subjects will be retested using the same method and at the same initial location for the second phase of tests, and the results will be compared.

Method of measurement

AST, ALT, and ALP are measured by the colorimetric method.

Secondary outcomes

1

Description

Blood sugar indices

Timepoint

Before the intervention, that is, at the beginning of the study, patients will be evaluated for blood sugar. After 8 weeks from the start of the intervention, all individuals will be retested using the same method and at the same initial location for the second phase of tests, and the results will be compared.

Method of measurement

At the beginning and end of the study, FBS (fasting blood sugar), and fasting insulin, were measured after a 12-hour fast and two indices QUIKI and HOMA-IR were calculated. FBS was measured by the enzymatic colorimetric method. Fasting insulin was measured by the enzyme immunoassay method. The QUIKI index was used to calculate insulin sensitivity. To calculate the QUIKI index, fasting insulin was used in the U/mlμ scale and fasting glucose was used in the mg/dl scale:QUIKI = 1 / [log (FI) + log (FG)]The HOMA-IR index was used to calculate insulin resistance. To calculate the HOMA-IR index, fasting insulin in U/lμ and fasting glucose in nmol/l are used: HOMA-IR = fasting insulin (μU/L) x fasting glucose (nmol/L)/22.5

2

Description

lipid profile indices

Timepoint

Before the intervention, that is, at the beginning of the study, patients will be evaluated for lipid profile. After 8 weeks from the start of the intervention, all individuals will be retested using the same method and at the same initial location for the second phase of tests, and the results will be compared.

Method of measurement

At the beginning and end of the study, serum cholesterol, LDL, HDL, and TG are measured using the enzymatic colorimetric method.

3

Description

liver functional enzymes

Timepoint

Before the intervention, that is, at the beginning of the study, patients will be evaluated for liver functional enzymes. After 8 weeks from the start of the intervention, all individuals will be retested using the same method and at the same initial location for the second phase of tests, and the results will be compared.

Method of measurement

At the beginning and end of the study ALT, AST and Alp were measured after a 12-hour fast.. AST, ALT and ALP were measured by the colorimetric method.

Intervention groups

1

Description

Intervention group: The intervention group, under the supervision of a relevant specialist, in addition to common diabetes treatments, received 6 capsules daily containing 4 plants: black seed, fenugreek seeds, sumac, and purslane for 8 weeks.

Category

Treatment - Drugs

2

Description
Control group: Control group: The placebo group, in addition to common diabetes treatments, received 6 capsules containing Oisel daily for 8 weeks.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Shabani Diabetes Specialist Clinic
Full name of responsible person
Mehdi Salehi
Street address
Shahid Shabani Diabetes Specialist Clinic, Bagh zeresk, gharbagh, isfahan
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Sponsors / Funding sources

1

Sponsor
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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
Arak 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
Arak University of Medical Sciences
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Mehdi Salehi
Position
Assistant professor
Latest degree
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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
Not applicable

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

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable