Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

Evaluation of the effect of traditional Persian diabetes product (Tabashir tablet) on blood glucose level in patients with type 2 diabetes: a double-blind placebo-controlled clinical trial

Protocol summary

Study aim
Determining the effectiveness of the traditional medicinal product, diabetes pills (Qoras Tabashir), in comparison with standard treatment in controlling blood sugar in patients with type 2 diabetes.

Design
A double-blind randomized clinical trial

Settings and conduct
This study is conducted in the Diabetes Clinic of the Endocrine and Metabolism Center of Tehran University of Medical Sciences. The doctor and the patient do not know whether the prescribed product is a drug or a placebo.

Participants/Inclusion and exclusion criteria
Inclusion criteria 1. Age: thirty to sixty-five years 2. Uncontrolled type 2 diabetes 3. The amount of HbA1c is more than seven and less than eight and a half 4. At least one month has passed since adding the dose of anti-diabetic medicine or prescribing a new anti-diabetic medicine Exclusion criteria: 1- Glomerular filtration rate, less than 60 ml/min 2- Serum albumin, less than 4 grams per deciliter 3- High SGOT and SGPT more than three times the normal level 4- Pregnancy and breastfeeding or intention to become pregnant 5- Taking insulin along with oral diabetes medications

Intervention groups
Intervention group: In addition to the standard treatment of diabetes, one Tabashir capsule (500 mg) three times a day. Control group: In addition to the standard treatment, a placebo of the same weight and with an indistinguishable appearance, one capsule three times a day

Main outcome variables
Two-hour blood glucose and fasting blood glucose levels and HbA1c levels

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230307057648N1**
Registration date: **2024-01-08, 1402/10/18**
Registration timing: **prospective**

Last update: **2024-01-08, 1402/10/18**
Update count: **0**

Registration date
2024-01-08, 1402/10/18

Registrant information

Name
Mahbubeh Bozorgi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5521 4060

Email address
mahboubehbozorgi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-02-20, 1402/12/01

Expected recruitment end date
2025-02-19, 1403/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of traditional Persian diabetes product (Tabashir tablet) on blood glucose level in patients with type 2 diabetes: a double-blind placebo-controlled clinical trial

Public title
Effect of Tabashir tablet in treatment of diabetes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Uncontrolled type 2 diabetes Age 30-65 years HbA1c greater than 7 and lower than 8.5 Under treatment with oral diabetes medications (one or more drug groups) At least one month after increasing the dose of antidiabetic medicine or prescribing a new antidiabetic medicine

Exclusion criteria:
Glomerular filtration rate, lower than 60 ml per minute Serum albumin, lower than 4 g/dL SGOT and SGPT, three times higher than normal level Pregnancy and breastfeeding or intention to become pregnant Taking insulin along with oral diabetes medications

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **106**

Randomization (investigator's opinion)
Randomized

Randomization description
Diabetic patients are randomly divided into two groups "control, intervention" after examination and if they meet the criteria to enter the trial. The random block method with blocks of four will be used by using online websites for random allocation. A numerical code is defined for the random sequence, and people receive the numerical code in the same order as they enter and are placed in the corresponding group according to the block

Blinding (investigator's opinion)
Double blinded

Blinding description
Medicine and placebo are prepared with a completely similar appearance. The patient enters the plan with his consent and receiving full explanations, but he does not know whether he has received a drug or a placebo, and the doctor is not aware of whether the product he is giving to the patient is a drug or a placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Research Institute of Endocrine and Metabolism, Tehran university of medical sci

Street address
Tehran, Persian Gulf Highway (Tehran-Qom), Shahed University

City
Tehran

Province
Tehran

Postal code
3319118651

Approval date
2022-06-15, 1401/03/25

Ethics committee reference number
IR.TUMS.EMRI.REC.1401.008

Health conditions studied

1

Description of health condition studied
diabetes

ICD-10 code
E11

ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
blood sugar

Timepoint
Blood sugar measurement at the beginning of the study (before the start of the intervention) and three months after taking the Tabashir capsule

Method of measurement
Blood test

Secondary outcomes

1

Description
Lipid profile

Timepoint
At the beginning and end of three months of study

Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: One 500 mg Tabashir capsule three times a day. . Formulation (in w/w) Tabashir powder 13.2, licorice root solid extract 13.2, lettuce seed 26.5, purslane seed 20, Armenian bole 2.6, rose bud powder without sepals 6.6, Coriander leaf and stem powder 6.6, acacia extract powder 2.6, gum arabic powder 2.6, white sandal solid powder 2.6, gelnar solid powder 2.6, camphor solid powder 0.6

Category
Treatment - Drugs

2

Description
Control group: Receiving 500 mg placebo capsules containing starch

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Superspecialized Diabetes Clinic

Full name of responsible person
Mahbubeh Bozorgi

Street address
No. 4, Ostad Nejatollahi St., Tehran - Elkhebal St.

City
Tehran

Province
Tehran

Postal code
1411713139

Phone
+98 21 8880 8005

Email
mahboubehbozorgi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Ms. Salimi

Street address
Endocrine and Metabolism Research Institute, next to Dr. Shariati Hospital, Jalal Al Ahmad Highway, Tehran

City
Tehran

Province
Tehran

Postal code
1411713139

Phone
+98 21 8863 1298

Email
emrc@tums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
No

Title of funding source
Valiasr traditional medicine clinic (Dr.kordafshar clinic)

Proportion provided by this source
100

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
Other

Person responsible for general inquiries

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Mahbubeh Bozorgi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Traditional Medicine

Street address
Khalij Fars Expressway, Shahed university

City
Tehran

Province
Tehran

Postal code
3319118651

Phone
+98 21 5521 4060

Fax

Email
mahboubehbozorgi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahed University

Full name of responsible person
Mahbubeh Bozorgi

Position
Associate professor

Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Khalij Fars Expressway, Shahed university
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5521 4060
Fax
Email
mahboubehbozorgi@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Shahed University
Full name of responsible person
Mahbubeh Bozorgi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
Street address
Khalij Fars Expressway, Shahed university
City
Tehran
Province
Tehran
Postal code
3319118651
Phone
+98 21 5521 4060
Fax
Email
mahboubehbozorgi@gmail.com

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
Confidentiality principles will be observed in publishing patient information. The method and results section will be mentioned in full in the article that will be written from this research.
When the data will become available and for how long
Information will be available from the time the article is published.
To whom data/document is available
Method information and results are mentioned in the article and will be available to the public
Under which criteria data/document could be used
The information that is not published in the article will be provided to other researchers, if necessary, while maintaining privacy and confidentiality
From where data/document is obtainable
The information published in the article will be available to the public. To obtain other documents, you should contact the project manager.
What processes are involved for a request to access data/document
Contact with the project manager is done via email. Then, the request is reviewed by the project manager and, if necessary, by the ethics committee, so that if there is no ethical problem, it is possible to access the documents.
Comments