

# 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

mahboubbehbozorgi@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

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##### Province

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3319118651

##### Phone

+98 21 5521 4060

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahed University

##### Full name of responsible person

Mahbubeh Bozorgi

##### Position

Associate professor

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**Fax****Email**

mahboubbehbozorgi@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**