

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Sep 2026

### The Joint Effects of Dog-rose, Cranberry leaves, Cranberry Berries, Alfalfa, Fenugreek, Lemon Beebrush, Urtica, and Sumac for controlling blood glucose of patients with type II diabetes mellitus: A Phase 1-2 Randomized, Double-Blind, Placebo-Controlled Clinical Trial

#### Protocol summary

##### Study aim

To investigate the safety and combined effect of cranberry leaves, cranberry berries, alfalfa, fenugreek, lemon beebrush, urtica, dog-rose, and sumac on improving the glycemic profile of patients with type 2 diabetes mellitus compared to the placebo group.

##### Design

Two-arm multi-center phase 1-2 parallel group double-blind placebo-controlled trial on 60 patients. We will use block randomization.

##### Settings and conduct

The participants will be randomly selected from individuals with type 2 diabetes who refer to the clinics of Tabriz University of Medical Sciences. The duration of the current clinical trial will be 6 months. Participants will have four outpatient clinic visits. To compare quantitative variables with and without normal distribution between the two studied groups, independent t-test and Mann-Whitney test will be used, respectively. Repeated measure analysis will be used to analyze the variables over time.

##### Participants/Inclusion and exclusion criteria

Individuals between the ages of 18 and 70 who have been diagnosed with type 2 diabetes for at least one year according to the criteria of the World Health Organization will be included in the study. People who are pregnant or with a medical history of type 1 diabetes, cardiovascular disease, thyroid disease, kidney disease, cancer, mental disorders, and taking drugs related to the mentioned diseases will not enter.

##### Intervention groups

The mixture of the extracts of cranberry leaves, cranberry berries, alfalfa, fenugreek, lemon beebrush, urtica, dog-rose, and sumac are prepared using the supercritical fluid extraction method. Then the extracts are formulated as a powder with maltodextrin as an

excipient and filled into capsules (500 mg). Each active capsule contains 200 mg of mixed extracts with an equal share of each plant. Placebo capsules consist only of maltodextrin.

##### Main outcome variables

The main goal is FBS change.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220614055167N1**

Registration date: **2023-01-19, 1401/10/29**

Registration timing: **prospective**

Last update: **2023-01-19, 1401/10/29**

Update count: **0**

##### Registration date

2023-01-19, 1401/10/29

##### Registrant information

##### Name

Saeid Safiri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 3332 7195

##### Email address

saeidsafiri@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-02-28, 1401/12/09  
**Expected recruitment end date**  
 2024-02-28, 1402/12/09  
**Actual recruitment start date**  
 empty  
**Actual recruitment end date**  
 empty  
**Trial completion date**  
 empty

**Scientific title**  
 The Joint Effects of Dog-rose, Cranberry leaves, Cranberry Berries, Alfalfa, Fenugreek, Lemon Beebrush, Urtica, and Sumac for controlling blood glucose of patients with type II diabetes mellitus: A Phase 1-2 Randomized, Double-Blind, Placebo-Controlled Clinical Trial

**Public title**  
 Dog-rose, Cranberry leaves, Cranberry Berries, Alfalfa, Fenugreek, Lemon Beebrush, Urtica and Sumac in diabetes mellitus

**Purpose**  
 Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
 At least one year of diagnosis of type 2 diabetes according to the criteria of the World Health Organization Hemoglobin A1c (HbA1c) > 7.0% or fasting blood glucose > 7.0 mmol/L, Body mass index (BMI) more than 23 kg/m<sup>2</sup> and less than 35.  
**Exclusion criteria:**  
 Comorbidities, including type 1 diabetes, cardiovascular disease, thyroid disease, kidney disease, cancer, mental disorders, and the use of drugs related to the aforementioned diseases Pregnancy Patients with a BMI over 35 who were on a weight loss diet or had taken weight loss supplements for less than 6 months A history of allergy to one of the components of the nestling fruit, carob leaf, carob fruit, alfalfa seed, fenugreek seed, lemon, Nettles, and sumac Lactating women Regularly consuming cigarettes or alcohol Using psychiatric drugs or insulin Changing the medication regimen during the trial period. For example, to start receiving insulin therapy, become pregnant, or no longer follow medication and dietary instructions

**Age**  
 From **18 years** old to **70 years** old

**Gender**  
 Both

**Phase**  
 1-2

**Groups that have been masked**

- Participant
- Care provider
- Investigator

**Sample size**  
 Target sample size: **60**

**Randomization (investigator's opinion)**  
 Randomized

**Randomization description**

Using block randomization, patients will be assigned to intervention groups or placebo groups. The randomization sequence will be determined by one of the individuals who did not participate in the current research. It is necessary to explain that the aforementioned randomization method reduces the possibility of predicting and manipulating the randomization process by people to zero and will lead to the balance of the size of the groups during and at the end of the study.

#### **Blinding (investigator's opinion)**

Double blinded

#### **Blinding description**

The patients will receive the boxes sealed with 10-digit codes and will receive the original drug or placebo, and they will not be aware of the type of received material. The researcher will ensure the blinding of the patients. Also, doctors, researchers, and those responsible for the implementation of the project will not be aware of the type of medicine received by the patients until the end of the study.

#### **Placebo**

Used

#### **Assignment**

Parallel

#### **Other design features**

### **Secondary Ids**

empty

### **Ethics committees**

#### **1**

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

##### **Street address**

Golgasht

##### **City**

Tabriz

##### **Province**

East Azarbaijan

##### **Postal code**

5166/15731

#### **Approval date**

2022-12-05, 1401/09/14

#### **Ethics committee reference number**

IR.TBZMED.REC.1401.827

#### **2**

#### **Ethics committee**

##### **Approval date**

empty

##### **Ethics committee reference number**

### **Health conditions studied**

## 1

### **Description of health condition studied**

Diabetes mellitus type 2

### **ICD-10 code**

E11

### **ICD-10 code description**

Type 2 diabetes mellitus

## **Primary outcomes**

## 1

### **Description**

Fasting blood glucose

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Glucometer

## **Secondary outcomes**

## 1

### **Description**

Insulin level

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Human Insulin ELISA Test Kit

## 2

### **Description**

Hemoglobin A1c level

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

HbA1c Reagent Kit

## 3

### **Description**

High density lipoprotein (HDL) levels

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Laboratory kits

## 4

### **Description**

Low density lipoprotein (LDL) levels

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Laboratory kits

## 5

### **Description**

Triglyceride level

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Laboratory kits

## 6

### **Description**

Total cholesterol levels

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Laboratory kits

## 7

### **Description**

Aspartate transaminase level

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Laboratory kits

## 8

### **Description**

Alanine aminotransferase level

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Laboratory kits

## 9

### **Description**

Blood urea nitrogen level

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Laboratory kits

## 10

### **Description**

Creatinine level

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Laboratory kits

## 11

### **Description**

Prothrombin time

### **Timepoint**

Day 0, 15, 90, 180 post intervention

### **Method of measurement**

Laboratory kits

## 12

### **Description**

Bilirubin level

### **Timepoint**

Day 0, 15, 90, 180 post intervention

**Method of measurement**

Laboratory kits

**13****Description**

Ferritin level

**Timepoint**

Day 0, 15, 90, 180 post intervention

**Method of measurement**

Laboratory kits

**14****Description**

Cholinesterase level

**Timepoint**

Day 0, 15, 90, 180 post intervention

**Method of measurement**

Laboratory kits

**15****Description**

High-sensitivity C-reactive protein level

**Timepoint**

Day 0, 15, 90, 180 post intervention

**Method of measurement**

Laboratory kits

**Intervention groups****1****Description**

Intervention group: Capsules containing dog-rose, Cranberry leaves, Cranberry Berries, Alfalfa, Fenugreek, Lemon Beebrush, Urtica, and Sumac

**Category**

Treatment - Drugs

**2****Description**

Control group: Placebo capsules containing maltodextrin

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Tabriz University of Medical Sciences

**Full name of responsible person**

Saeid Safiri

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Tabriz University of Medical Sciences

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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**

Tabriz 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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Saeid Safiri

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

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**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Saeid Safiri

**Position**

Assistant Professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Epidemiology

**Street address**

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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

Yes - There is a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

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

### Title and more details about the data/document

All of the information will be available to all after publishing without the personal information of participants.

### When the data will become available and for how long

After publishing the papers

### To whom data/document is available

All researchers that are confirmed by the principal investigator

### Under which criteria data/document could be used

All of the data will be available except the personal information of the participants

### From where data/document is obtainable

The principal investigator

### What processes are involved for a request to access data/document

It is evaluated by the team and the principal investigator will inform those who requested

### Comments