Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 investigates 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/m2 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
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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
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Saeid Safiri
Position
Assistant professor
Latest degree
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Other areas of specialty/work
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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