Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Urtica Dioica (Nettle), Vaccinium myrtillus on blood glucose parameters and lipid profile in patients with type 2 diabetes: a double-blind clinical trial

Protocol summary

Study aim

Determining the effect of Urtica Dioica, Vaccinium myrtillus on blood glucose parameters and lipid profile in patients with type 2 diabetes

Design

Double-blind randomized clinical trial with two groups: Urtica Dioica, Vaccinium myrtillus, and placebo

Settings and conduct

The study will be conducted at Imam Reza Hospital. Patients will be randomly divided into two groups of Urtica Dioica, Vaccinium myrtillus, and placebo by block method. The researchers and participants will not be aware of the groups involved).

Participants/Inclusion and exclusion criteria

Type 2 diabetes, Taking hypoglycemic drugs, Age 40-70 years, Body mass index 18.5–30 kg / m 2, Fasting blood sugar equal to or more than 126 mg / d exclusion criteria: Type 1 diabetes, Other specific types of diabetes, Insulin therapy over the past three months, Having serious gastrointestinal diseases (GI), Have a history of diabetic ketoacidosis, non-ketotic hyperosmolar diabetic coma, severe infection or surgery in the previous month, Uncontrolled high blood pressure, mental illness, Abuse or addiction to alcohol, psychoactive substances or other drugs, Pregnancy, lactation or plan to become pregnant, Having cardiovascular disease, renal insufficiency, liver dysfunction, thyroid dysfunction, parathyroid dysfunction, and cancers, High physical activity, Chronic complications of diabetes (neuropathy, retinopathy, according to patient records), diabetic nephropathy, hypothyroidism and hyperthyroidism, Sensitivity to nettle, Vaccinium myrtillus

Intervention groups

The Urtica Dioica, Vaccinium myrtillus recipient will receive a capsule (500 mg) containing 300 mg of Urtica Dioica and 150 mg Vaccinium myrtillus every 12 hours. The placebo group will receive a 500 mg placebo capsule every 12 hours.

Main outcome variables

Fasting blood sugar amount that will be checked with blood tests before starting the drug and three months later

General information

Reason for update

Impossibility to provide the drugs through the company due to coronary conditions

Acronym

IRCT registration information

IRCT registration number: **IRCT20140617018126N3**
Registration date: **2020-06-09, 1399/03/20**
Registration timing: **prospective**

Last update: **2021-02-22, 1399/12/04**
Update count: **1**

Registration date

2020-06-09, 1399/03/20

Registrant information

Name
Mostafa Araj-Khodaei
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-09-22, 1400/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Urtica Dioica (Nettle), Vaccinium myrtillus on blood glucose parameters and lipid profile in patients with type 2 diabetes: a double-blind clinical trial

Public title

The effect of Urtica Dioica (Nettle), Vaccinium myrtillus on type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes Taking hypoglycemic drugs (people who control their diabetes just by taking blood sugar-lowering drug) Age 40-70 years Body mass index 18.5–30 kg / m 2 Fasting blood sugar equal to or more than 126 mg / d

Exclusion criteria:

Type 1 diabetes Other specific types of diabetes Insulin therapy over the past three months Having serious gastrointestinal diseases (GI) including gastric ulcers and gastrointestinal bleeding Have a history of diabetic ketoacidosis, non-ketotic hyperosmolar diabetic coma, severe infection or surgery in the previous month Uncontrolled high blood pressure (Blood pressure higher or equal to 160/100 mm Hg) mental illness Abuse or addiction to alcohol, psychoactive substances or other drugs Pregnancy, lactation or plan to become pregnant Having cardiovascular disease, renal insufficiency, liver dysfunction, thyroid dysfunction, parathyroid dysfunction, and cancers High physical activity Chronic complications of diabetes (neuropathy, retinopathy, according to patient records), diabetic nephropathy, hypothyroidism and hyperthyroidism Sensitivity to Nettle and Vaccinium myrtillus

Age

From **40 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Samples will be randomly assigned to four blocks using Random Allocation Software. Blocking and allocation sequences for concealment will be done by the non-involved researcher (Allocation Concealment). The sample allocation ratio will be Allocation 1:1 and will be divided into two groups of receiving Urtica Dioica, Vaccinium myrtillus, and Placebo. Then based on blocks and allocation sequences each client will be given white pockets that are prepared in equal sizes and on which the numbers 1 to 60 are written (in order of allocation sequence). The pockets will contain white boxes containing Urtica Dioica, Vaccinium myrtillus, or Placebo capsules. Only the person in charge of packing Urtica Dioica, Vaccinium myrtillus, and Placebo capsules will know the numbers of the relevant pockets and none of the researchers or patients will know the type of medicine that each person receives. The first person will be given pocket number 1 and then it will continue until completion. Urtica Dioica, Vaccinium myrtillus, and placebo capsules will be similar in shape, size, color and, smell

Blinding (investigator's opinion)

Double blinded

Blinding description

Based on blocks and allocation sequences each client will be given white pockets that are prepared in equal sizes and on which the numbers 1 to 60 are written (in order of allocation sequence). The pockets will contain white boxes containing Urtica Dioica, Vaccinium myrtillus, or Placebo capsules. Only the person in charge of packing Urtica Dioica, Vaccinium myrtillus, and Placebo capsules will know the numbers of the relevant pockets and none of the researchers or patients will know the type of medicine that each person receives. The first person will be given pocket number 1 and then it will continue until completion. Urtica Dioica, Vaccinium myrtillus, and placebo capsules will be similar in shape, size, color, and smell.

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

Research Vice Chancellor, Third Floor, Central Building No. 2, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-04-20, 1399/02/01

Ethics committee reference number

IR.TBZMED.REC.1399.093

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Fasting Blood Sugar

Timepoint

Blood tests before starting the drug and three months later (after taking the drug completely)

Method of measurement

Fasting Blood Sugar Test

Secondary outcomes

1

Description

HbA1C

Timepoint

Blood tests before starting the drug and three months later (after taking the drug completely)

Method of measurement

HbA1C test

2

Description

Creatinine

Timepoint

Blood tests before starting the drug and three months later (after taking the drug completely)

Method of measurement

Creatinine Test

3

Description

Fasting Insulin

Timepoint

Blood tests before starting the drug and three months later (after taking the drug completely)

Method of measurement

Fasting Insulin Blood Test

4

Description

Cholesterol

Timepoint

Blood tests before starting the drug and three months later (after taking the drug completely)

Method of measurement

Cholesterol Test

5

Description

Triglyceride

Timepoint

Blood tests before starting the drug and three months later (after taking the drug completely)

Method of measurement

Triglyceride Test

Intervention groups

1

Description

Intervention group: This group will receive the capsules (500 mg) of Urtica Dioica, Vaccinium myrtillus containing 300 mg Urtica Dioica extract and 150 mg of Vaccinium myrtillus extract every 12 hours and for 3 months. The capsules will be provided by Sina Noandish Tabiat Company.

Category

Treatment - Drugs

2

Description

Control group: This group will receive the placebo capsules (500 mg) containing additives every 12 hours and for 3 months. The capsules will be provided by Sina Noandish Tabiat Company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam reza hospital

Full name of responsible person

Seyed Mostafa Araj khodaie

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1

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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

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available