

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Effect of combination of Chromium, Cinnamon, Urtica, eryngium and D.sophia on glycemic, antioxidant, inflammatory indices, lipid profile and HOMA index in type 2 diabetic patients

Protocol summary

Study aim

Effect of combination of Chrome, Cinnamon, Urtica, eryngium and D.sophia on glycemic, antioxidant, inflammatory indices, lipid profile and Homeostatic Model Assessment (HOMA) index in type 2 diabetic (T2DM) patients

Design

Individuals are divided into 2 groups of 30 intervention and placebo. The intervention group will receive a capsule containing herbal extract powder twice a day, and the placebo group will receive a capsule containing wheat flour, which looks exactly like the capsule of the intervention group, and the duration of the study will be 8 weeks.

Settings and conduct

The subjects will be selected from patients referred to the Endocrinology and Metabolism Clinic of Qazvin University of Medical Sciences. Individuals are divided into 2 groups of 30 intervention and placebo. Because supplements and placebos are similar in shape, participants and researchers are not aware that placebos or supplements are taken in each group. In the data analysis stage, the analyzer does not know the identity of the groups.

Participants/Inclusion and exclusion criteria

Volunteered Type 2 Diabetes Mellitus (T2DM) age 30 - 60
No change in treatment and medications in at least the last 2 months
Average level of physical activity
Body mass index between 25 and 30
Hemoglobin-A1C (HbA1C) between 7 and 9

Intervention groups

The intervention group will receive 2 mg daily capsules containing herbal extract powder for 2 months and the placebo group will receive capsules containing wheat flour similar to the capsules of the intervention group.

Main outcome variables

fbs HbA1c ins sensitivity HOMA-IR tc tg LDL HDL VLDL

CRP TNF α MDA

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210530051441N1**

Registration date: **2021-06-15, 1400/03/25**

Registration timing: **registered_while_recruiting**

Last update: **2021-06-15, 1400/03/25**

Update count: **0**

Registration date

2021-06-15, 1400/03/25

Registrant information

Name

Mohammad Reza Shiri Shahsavari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3336 9581

Email address

nutshiri@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-04, 1400/03/14

Expected recruitment end date

2021-09-05, 1400/06/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of combination of Chromium, Cinnamon, Urtica, eryngium and D.sophia on glycemic, antioxidant, inflammatory indices, lipid profile and HOMA index in type 2 diabetic patients

Public title

Effect of novel combination of herbal extracts in type 2 diabetic patients indices

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Volunteered Type 2 Diabetes Mellitus (T2DM) age 30 - 60
No change in treatment and medications in at least the last 2 months
Average level of physical activity body mass index between 25 and 30
HA1C between 25 and 30

Exclusion criteria:

Having diabetes for more than ten years
Pregnancy and lactation
Hospitalization during the study
Patients with severe renal and hepatic impairment and any other acute illness
Occurrence of any side effects due to the intervention
Menopause and hormone therapy
Diet change
Changes in the physical activity level
Taking any dietary supplement from 2 months before to the end of the study
History of any allergies

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Triple blinded

Blinding description

patients, researchers and statistical analyzer Individuals are divided into 2 groups of 30 intervention and placebo. Because supplements and placebos are similar in shape, participants and researchers are not aware that placebos or supplements are taken in each group. In the data analysis stage, the analyzer does not know the identity of the groups.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

qazvin university of medical sciences

Street address

qazvin university of medical sciences, bahonar blv.
qazvin iran

City

qazvin

Province

Qazvin

Postal code

3419759811

Approval date

2020-04-25, 1399/02/06

Ethics committee reference number

IR.QUMS.REC.1399.020

Health conditions studied**1****Description of health condition studied**

Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2**Description of health condition studied**

immune and anti-oxidant system

ICD-10 code

E00-E89

ICD-10 code description

Diseases of the blood and blood-forming organs and certain disorders involving the immune mechanism

Primary outcomes**1****Description**

Fasting Plasma Glucose (FBS)

Timepoint

Benign of the study and after 8 weeks in the end of the study

Method of measurement

Biochemistry tests

Secondary outcomes

1

Description

Plasma insuline

Timepoint

Benign of the study and after 8 weeks in the end of the study

Method of measurement

Biochemistry tests

Intervention groups

1

Description

Group 1 - Intervention: In this group, patients will receive 100 mg capsules containing herbal extract powder twice a day. The extracts have been purchased and the final combination formulated. Patients will first be interviewed by a trained nutritionist and questionnaires related to the general conditions and anthropometric measurements will be completed.

Category

Treatment - Other

2

Description

Group 2 - Placebo: They will receive a capsule containing wheat flour and very similar to the capsules of the intervention group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital - Qazvin

Full name of responsible person

Mohammad Reza Shiri Shahsavari

Street address

Qazvin University of Medical Sciences, Bahonar blv,
Qazvin Iran

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3336 9581

Email

nutshiri@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Reza Shiri Shahsavari

Street address

Qazvin University of Medical Sciences, Bahonar blv,
qazvin

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3336 9581

Email

nutshiri@gmail.com

Grant name

Vice Chancellor for Research and Technology of Qazvin
University of Medical Sciences

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Reza Shiri Shahsavari

Position

assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

Street address

qazvin university of medical sciences, Bahonar blv,
qazvin

City

qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3336 9581

Email
nutshiri@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohammad Reza Shiri Shahsavari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Qazvin University of Medical Sciences, Bahonar blv,
Qazvin
City
Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3336 9581
Email
nutshiri@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Mohammad Reza Shiri Shahsavari
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Qazvin University of Medical Sciences, Bahonar blv,
Qazvin
City
Qazvin
Province
Qazvin

Postal code
3419759811
Phone
+98 28 3336 9581
Email
nutshiri@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Not applicable

Title and more details about the data/document

The data will be published in the thesis and article

When the data will become available and for how long

At most 6 months

To whom data/document is available

It will be available to everyone, such as individuals, scientific institutes, industry

Under which criteria data/document could be used

Thesis data will be made available to students and researchers to use the results of plant extracts on the study variables if necessary.

From where data/document is obtainable

Published database and valid journals and, By email to the executive and corresponding author: "nutshiri@gmail.com" and cell No. 09143016970, Or refer to the library of Qazvin University of Medical Sciences, Qazvin Bahonar Blvd., Qazvin University of Medical Sciences, telephone number 02833336001 and site address www.qums.ac.ir.

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

By email to the executive and corresponding author: "nutshiri@gmail.com" and cell No. 09143016970, Or refer to the library of Qazvin University of Medical Sciences, Qazvin Bahonar Blvd., Qazvin University of Medical Sciences, telephone number 02833336001 and site address www.qums.ac.ir.

Comments