Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 7and 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 TNFα 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 Shahsavar

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 statiscal anlyser 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, bahanor 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 Shahsavar
Street address
Qazvin University of Medical Scienses, Bahonar blv, Qazvin Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
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Mohammad Reza Shiri Shahsavar
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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 Shahsavar
Position
assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
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Person responsible for scientific inquiries

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Person responsible for updating data

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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