Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The Effect of Co-supplementation of Curcumin and Amla on lipid profile, Glycemic status, Antioxidant Indices, Inflammatory Factor, and Liver Enzymes in Patients with Type 2 Diabetes: A Double-Blind Randomized Clinical Trial

Protocol summary

Study aim
The Co-supplementation of Curcumin and Amla on lipids, Glycemic status, Inflammatory factor, Antioxidant indices, and liver enzymes in Patients with DM2

Design
parallel, double-blind ، randomized.

Settings and conduct
Participants with type 2 diabetes are referred to the diabetes clinic of Bushehr University of Medical Sciences, and will be diagnosed by an endocrinologist. they will be divided into two groups of 25 patients receiving Curcumin +Amla and placebo supplementation. patients receiving Curcumin and Amla 2 capsules daily 500 mg (250mg Curcumin +250mg Amla) and patients in the placebo group also take 2 capsules that are similar in appearance to intervention supplements half an hour after the main meal for 12 weeks. Cans containing capsules and how to use them were coded by a non-researcher as allocation concealment for lack of observing the type of received capsule information.

Participants/Inclusion and exclusion criteria
Inclusion criteria (1 year history of diabetes, age 25 to 65 , BMI 25 and 34.9, taking blood sugar oral medications, informed consent. Exclusion criteria;, (suffering from chronic diseases (liver, kidney, heart, thyroid, rheumatic, pulmonary, metabolic, digestive, malignancies, allergies) pregnancy, breastfeeding, insulin treatment and... etc.)

Intervention groups
Patients are randomly divided into two groups of 25 patients receiving curcumin and Amla and placebo supplementation. In this study, patients are given the supplements for 12 weeks, half an hour after the main meal.. Patients who received 2 capsules of curcumin and Amla (250mg curcumin +250mg Amla) and patients who are in the group receiving placebo (wheat flour) 2capsules daily500 mg, which are similar in appearance to intervention supplements.

Main outcome variables
Lipid profile, Glycemic indices, Antioxidant indices, Inflammatory factor, and liver enzymes

General information

Reason for update
the anthropometry measurement of BMI as secondary outcome has been requested for updating

Acronym

IRCT registration information
IRCT registration number: **IRCT20220902055853N1**
Registration date: **2022-10-10, 1401/07/18**
Registration timing: **prospective**

Last update: **2024-01-10, 1402/10/20**
Update count: **2**

Registration date
2022-10-10, 1401/07/18

Registrant information

Name
fatemeh borazjani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 61 3321 9570

Email address
fa.borazjani@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date

2022-10-23, 1401/08/01

Expected recruitment end date

2023-04-21, 1402/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Co-supplementation of Curcumin and Amla on lipid profile, Glycemic status, Antioxidant Indices, Inflammatory Factor, and Liver Enzymes in Patients with Type 2 Diabetes: A Double-Blind Randomized Clinical Trial

Public title

Effect of Co-supplementation of Curcumin and Amla in Patients with Type 2 Diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals who are diagnosed with T2DM for at least one years ago Age range from 25 to 65 years BMI range between 25 to 34.9 kg/m2 Taking oral blood sugar lowering drugs to control diabetes Consent to participate in the study

Exclusion criteria:

Having chronic diseases (liver, kidney, heart, thyroid, rheumatic, pulmonary, metabolic, digestive, malignancies, allergies) Pregnancy lactation Insulin treatment Taking food supplement, vitamin and mineral for at least in the last 3 months Taking other medicinal plants routinely for at least in the last 3 months Having a weight loss diet for at least in the last6 months Smoking Taking drugs or alcohol in the last 6 months Taking steroid anti-inflammatory drugs and fiber supplements Participate in another trial at the same time

Age

From **25 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done individually. The entry of each patient into the Intervention or Control group is distributed in each group using the Randomization method with the help of four blocks. This work is done by using a sequence of random numbers generated by Sealed Envelope Ltd. 2022. Create a blocked randomization list. [Online] Available from: https://www.sealedenvelope.com/simple-randomiser/v1/lists

Blinding (investigator's opinion)

Double blinded

Blinding description

The study will be double-blinded, hence the researcher and participants will not know which group they belong to. For blinding, intervention and placebo capsules are provided in similar shapes, colors, and sizes. These capsules are coded by a person other than the investigators (A and B) and then the capsules are given to participants. Until the end of the study and after analyzing the data, investigators will not know about the intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Ahvaz Jundishapur university of medical sciences,Ahvaz,Iran.

Street address

Academic City - Ahvaz - University of Medical Sciences and Health Care Services Ahvaz - Research and Technology Development Deputy Building - Nutrition and Metabolic Diseases Research Center

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2022-08-13, 1401/05/22

Ethics committee reference number

IR.AJUMS.REC.1401.196

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 glucose
Timepoint
At the beginning and end of study
Method of measurement
Serum sample

2

Description
Hemoglobin A1c
Timepoint
At the beginning and end of study
Method of measurement
Serum sample

3

Description
Fasting Insulin
Timepoint
At the beginning and end of study
Method of measurement
Serum sample

4

Description
hs Crp
Timepoint
At the beginning and end of study
Method of measurement
Sample serum

5

Description
Insulin Sensitivity
Timepoint
At the beginning and end of study
Method of measurement
Formula based

6

Description
Insulin resistance
Timepoint
Aat the beginning and end of study
Method of measurement
Formula based

Secondary outcomes

1

Description
Systolic and Diastolic Blood Pressure
Timepoint
At the beginning,and end of the study
Method of measurement
mercury sphygmomanometer

2

Description
Dietary intake (Energy, Carbohydrate, Fat, Protein)
Timepoint
At the beginning, and end of the study
Method of measurement
Using Nutritionist IV software

3

Description
Physical Activity
Timepoint
At the beginning,and end of the study
Method of measurement
Short form of the International Physical Activity Questionnaire (IPAQ-SF)

4

Description
Health-related Quality of life
Timepoint
At the beginning, and end of the study
Method of measurement
SF-12 questionnaire

5

Description
Serum triglyceride
Timepoint
At the begin and end of study
Method of measurement
Serum sample

6

Description
Total cholesterol
Timepoint
At the begin and end of study
Method of measurement
Serum sample

7

Description
Serum Low Density lipoprotein -Cholesterol (LDL-C)
Timepoint
At the begin and end of study
Method of measurement
Serum sample

8

Description
Serum high Density lipoprotein -Cholesterol (HDL-C)
Timepoint

At the begin and end of study

Method of measurement

Serum sample

9

Description

Malondialdehyde (MDA

Timepoint

At the begin and end of study

Method of measurement

Serum sample

10

Description

Total Antioxidant Capacity (TAC)

Timepoint

At the begin and end of study

Method of measurement

Serum sample

11

Description

Superoxide dismutase (SOD)

Timepoint

At the begin and end of study

Method of measurement

Serum sample

12

Description

Aspartate Transaminase (AST)

Timepoint

At the begin and end of study

Method of measurement

Serum sample

13

Description

Alanine Transaminase (ALT)

Timepoint

At the begin and end of study

Method of measurement

Serum sample

14

Description

Gamma-Glutamyl Transferase (GGT)

Timepoint

At the begin and end of study

Method of measurement

Serum sample

15

Description

body mass index

Timepoint

At the begin and end of study

Method of measurement

Height and weight measurement with scale with the accuracy of 0.1and apply it in the BMI formula

Intervention groups

1

Description

Intervention group: Co-supplementation of Curcumin + Amla (curcumin 250 mg and Amla 250 mg, 2 capsules of 500 mg daily) half an hour after main meals for period of 12 weeks

Category

Treatment - Drugs

2

Description

Control group: Daily 2 capsules of 500 mg containing roasted rice powder as placebo half an hour after main meals for 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes Clinic of Bushehr University of Medical Sciences

Full name of responsible person

Maryam Behrouzi

Street address

Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khouzestan, Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135815751

Phone

+98 917 022 9874

Email

mbehroozi474@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Mehrnoosh Zakerkish

Street address

Ahvaz Jundishapur University of Medical Sciences، Deputy of research and technology Address: Ahvaz Jundishapur University of Medical Sciences، Deputy of

research and technology،Ahvaz, Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 2414
Email
itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Maryam Behrouzi
Position
MSc Sstudent
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Golestan Medical Sciences Dormitory, Golestan Boulevard, Ahvaz, Khouzestan, Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135815751
Phone
+98 77 3344 6968
Email
mbehroozi474@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Fatemeh Borazjani
Position
Assistant Professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Golestan Boulevard- Golestan- department of nutrition-Jundishapur university of Medical Sciences-Ahvaz-Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3311 2665
Email
fa.borazjani@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Maryam Behrouzi
Position
Student
Latest degree
Bachelor
Other areas of specialty/work
Nutrition
Street address
Naval Base, Navy Martyrs Street, Bushehr
City
Bushehr
Province
Boushehr
Postal code
7518614146
Phone
+98 77 3344 6968
Email
mbehroozi474@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
No - There is not 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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The effect of Co-supplementation of Curcumin and Amla on lipid profile, Glycemic status, Inflammatory factor, Antioxidant indices, and liver enzymes in patients with type 2 diabetes: A Double-Blind Randomized clinical trial

When the data will become available and for how long

After the publication of the article

To whom data/document is available

All

Under which criteria data/document could be used

study

From where data/document is obtainable

Fatemeh Borazjani

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

E mail

Comments