

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

24 Jun 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/m<sup>2</sup> 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 last 6 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/lits>

**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**

Khuzestan

**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**

At 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 0.1 and 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, Khuzestan, Iran  
**City**  
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**Province**  
Khuzestan  
**Postal code**  
6135815751  
**Phone**  
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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**

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**Province**

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**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

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## 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

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Golestan Boulevard- Golestan- department of nutrition-Jundishapur university of Medical Sciences- Ahvaz-Iran

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## 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

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**Province**

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**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**