

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Aug 2026

The investigating of the effect of curcumin and zinc co-supplementation on glycemic measurements, lipid profiles, inflammatory and antioxidant biomarkers in pre-diabetic patients

Protocol summary

Study aim

The determining of the effect of curcumin and zinc co-supplementation on glycemic measurements, lipid profiles, inflammatory and antioxidant biomarkers in pre-diabetic patients

Design

a double-blind randomized controlled trial/ factorial design/ 4 parallel groups: (N=21)

Settings and conduct

84 patients referring to Yazd Diabetes Specialty Clinic who meet the inclusion criteria will be randomly divided into 4 groups by random sampling. General Characterization and the assessment of anthropometric, diet, Weight loss, physical activity, and biochemistry will conduct for each patient. After 3 months of supplementation, the above assessment will be re-evaluated.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Both genders age: 18-50 years, prediabetic patients, BMI=25-35 No use of blood glucose-lowering drugs, written informed consent from patients
Exclusion criteria: Having a history of gestational diabetes,- Pregnancy or lactation in women, Use of multivitamin-mineral supplements from three months before and during the intervention, a history of weight loss surgery in the last year, weight loss plan in the last 3 months, Sensitivity to supplementation or non-compliance during the intervention, Simultaneously participate in another project, Unwillingness to continue cooperation

Intervention groups

pre-diabetes patients

Main outcome variables

insulin, fasting glucose, HbA1c, insulin resistance, insulin sensitivity, beta-cell function, serum triglyceride, serum total cholesterol, serum LDL-C, HDL-C, ALT, AST, TAC, MDA, serum zinc, IL-1B, CRP, hs-CRP,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190902044671N1**

Registration date: **2019-10-11, 1398/07/19**

Registration timing: **prospective**

Last update: **2020-11-13, 1399/08/23**

Update count: **1**

Registration date

2019-10-11, 1398/07/19

Registrant information

Name

Maryam Azhdari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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azhdari_mar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-11-11, 1398/08/20

Expected recruitment end date

2020-05-21, 1399/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The investigating of the effect of curcumin and zinc co-supplementation on glycemic measurements, lipid profiles, inflammatory and antioxidant biomarkers in pre-diabetic patients

Public title

The investigating of the effect of curcumin and zinc co-supplementation on glycemic measurements, lipid profiles, inflammatory and antioxidant biomarkers in pre-diabetic patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

both genders age: 18-50 years (for women 18 years before menopause individuals with IFG =100-125 (mg/dL), IGT =140-199(mg/dL), or/and HbA1c=% 6.4 -5.7 , individuals with BMI=25-35 No use of blood glucose-lowering drugs such as Metformin or Glucophage individuals with written informed consent from patients

Exclusion criteria:**Age**

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

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

Sample size

Target sample size: **84**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to prevent selection bias from occurring after randomization, the concealment allocation method will be used to assign binary codes to each individual.

Blinding (investigator's opinion)

Double blinded

Blinding description

Before starting the study, a person other than the researchers will code the packages including two cans according to the number of participants in the study to keep the researcher informed about the type of pills received by each group. Each individual is delivered a pack including two cans. On each can, how to use the pills will be explained. Package 1 will contain (can1: placebo for curcumin supplement (bb), and can 2: zinc supplement (AA)); package 2 will contain (can1: placebo for zinc supplement (aa), and can 2: curcumin supplement (BB)); Package 3 will contain (can 1: zinc supplementation (AA) and can 2: curcumin supplementation (BB)), package 4 will contain (can 1: placebo for curcumin supplement (aa), and can 2: placebo for zinc supplement (bb)).

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences, Golestan high way, Ahvaz, Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Approval date

2019-10-05, 1398/07/13

Ethics committee reference number

IR.AJUMS.REC.1398.504

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

Pre-diabetic

ICD-10 code

R-73.0

ICD-10 code description

Abnormal glucose tolerance test

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

Fasting blood glucose

Timepoint

at the beginning and end of study

Method of measurement

serum sample

2**Description**

serum insulin

Timepoint

at the beginning and end of study

Method of measurement

serum sample

3

Description

hemoglobin A1c

Timepoint

at the beginning and end of study

Method of measurement

serum sample

4

Description

serum triglyceride

Timepoint

at the beginning and end of study

Method of measurement

serum sample

5

Description

insulin resistance

Timepoint

at the beginning and end of study

Method of measurement

insulin resistance formula (HOMA-IR)

6

Description

insulin sensitivity

Timepoint

at the beginning and end of study

Method of measurement

insulin sensitivity formula

7

Description

beta-cell function

Timepoint

at the beginning and end of study

Method of measurement

formula

8

Description

total cholesterol

Timepoint

at the beginning and end of study

Method of measurement

serum sample

9

Description

serum Low Density lipoprotein -Cholesterol (LDL-C)

Timepoint

at the beginning and end of study

Method of measurement

serum sample

10

Description

serum Low Density lipoprotein -Cholesterol (HDL-C)

Timepoint

at the beginning and end of study

Method of measurement

serum sample

11

Description

Malondialdehyde (MDA)

Timepoint

at the beginning and end of study

Method of measurement

serum sample

12

Description

Total Antioxidant Capacity (TAC)

Timepoint

at the beginning and end of study

Method of measurement

serum sample

13

Description

serum zinc

Timepoint

at the beginning and end of study

Method of measurement

serum sample

14

Description

interleukin 1-B (IL-1B)

Timepoint

at the beginning and end of study

Method of measurement

serum sample

15

Description

C- Reaction Protein (CRP)

Timepoint

at the beginning and end of study

Method of measurement

serum sample

16

Description

High sensitivity C- Reaction Protein(hs-CRP)

Timepoint

at the beginning and end of study

Method of measurement

serum sample

Secondary outcomes

1

Description

Aspartate Transaminase (AST)

Timepoint

at the beginning and end of study

Method of measurement

serum sample

2

Description

Alanine Transaminase (ALT)

Timepoint

at the beginning and end of study

Method of measurement

serum sample

3

Description

weight

Timepoint

at the beginning, and end of the study

Method of measurement

seca scales

4

Description

height

Timepoint

at the beginning

Method of measurement

stadiometer

5

Description

waist circumference

Timepoint

at the beginning, and end of the study

Method of measurement

tape

6

Description

hip circumference

Timepoint

at the beginning, and end of the study

Method of measurement

tape

7

Description

blood pressure

Timepoint

at the beginning, and end of the study

Method of measurement

Korotkoff sound technique with a calibrated mercury sphygmomanometer

8

Description

Body composition (fat mass (FM), free fat mass (FFM), muscle mass (MM))

Timepoint

at the beginning, and end of the study

Method of measurement

bioelectrical impedance analysis (BIA) method by a Body Composition Analyzer (InBody 270, Seoul, South Korea)

9

Description

Dietary intake (energy, carbohydrate, fat, protein)

Timepoint

at the beginning, and end of the study

Method of measurement

using Nutritionist IV software

10

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)

11

Description

Health-related quality of life

Timepoint

at the beginning, and end of the study

Method of measurement

SF-36 questionnaire

Intervention groups

1

Description

Intervention group: curcumin supplement

Category

Treatment - Drugs

2

Description

Intervention group: zinc supplement

Category

Treatment - Drugs

3

Description

Intervention group: curcumin supplement+zinc supplement

Category
Treatment - Drugs

4

Description
Control group: placebo

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd Diabetes Research Clinic

Full name of responsible person
Maryam Azhdari

Street address
Shahid bahonar Square, shihid sadoughi BLv, Yazd, Iran.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ahvaz University of Medical Sciences

Full name of responsible person
Dr.Mohammad.Badavi

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Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source
Ahvaz Jundishapur University of Medical Sciences, Ahvaz, Iran,

Proportion provided by this source
60

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

2

Sponsor

Name of organization / entity
Yazd University of Medical Sciences

Full name of responsible person
Dr.Masood.Mirzaei

Street address
Shahid Sadoughi University of Medical Sciences and Health Services, Shahid bahonar Square, shihid sadoughi BLv, Yazd, Iran.

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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
Yazd University of Medical Sciences

Proportion provided by this source
40

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 Azhdari

Position

Ph.D Student

Latest degree

Master

Other areas of specialty/work

Nutrition

Street address

Department of clinical biochemistry, Faculty (school) of Medicine, Shahid Sadoughi University of Medical Sciences and Health Services, Saffaeieh, Alem Square, Shohadaye Gomnan BLv, Yazd, Iran.(Postal Code: 8916178477)

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

all data is related to primary and secondary outcome, will be reported.

When the data will become available and for how long

After the manuscript publication.

To whom data/document is available

After publication, it will be possible for everyone.

Under which criteria data/document could be used

Using the documentation with citation 1- To conduct

similar and extensive research 2- To use the method of a project 3. To write systematic Review and meta-analysis articles

From where data/document is obtainable

1- Refer to the Library of Ahvaz Jundishapur University of Medical Sciences 1-Refer to the Library of Yazd University of Medical Sciences 3- Email to Maryam Azdari: azhdari_mar@yahoo.com)

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

Everyone can use the data Referring to the library of the above-mentioned universities or by the emailing, for received data by email, it will be necessary to explain the reason for the using the data completely and clearly. He/she will be received within a maximum of one week.

Comments