Clinical Trial Protocol
Iranian Registry of Clinical Trials

25 Jun 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

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Iran (Islamic Republic of)

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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

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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
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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

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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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Other areas of specialty/work
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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