

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Examining the effect of Curcumin on fasting blood sugar and insulin resistance index in prediabetic individuals

Protocol summary

Study aim

Examining the effect of Curcumin on fasting blood sugar and insulin resistance index in prediabetic individuals

Design

Triple-blind parallel randomized clinical trial with control group, phase 2-3 on 56 patients. We will use the website (www.sealedenvelope.com) for randomization.

Settings and conduct

Prediabetic individuals with mentioned inclusion criteria that refer to endocrinology clinic of university hospitals or private clinics in Mashhad, will be enrolled to this study after informed consent. They will be divided into two groups of intervention (curcumin) and control (placebo). The study period is 3 months. Fasting Blood Sugar (FBS), HOMA-IR, HbA1C, insulin, and CRP will be assessed and compared between two groups at baseline and after 3 months.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Individuals aged 18-70 years with prediabetes status, Satisfaction for participation in research project. Exclusion Criteria: Using anti diabetic drugs or other drugs which affect on blood sugar such as Thiazide, Glucocorticoids, and Anti-psychotics; Systemic disorders such as hepatic or renal failure; Oral intolerance; Using anti-coagulant drugs.

Intervention groups

Intervention group: Curcumin tablet daily (contains 500 mg Curcumin and 5 mg Piperine). Control group: placebo (similar to intervention in shape, size and color)

Main outcome variables

FBS (Fasting Blood Sugar), HOMA-IR, HbA1C, insulin, CRP at baseline and after 3 months

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181022041407N2**

Registration date: **2023-01-28, 1401/11/08**

Registration timing: **prospective**

Last update: **2023-01-28, 1401/11/08**

Update count: **0**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name

Maryam Emadzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-02-20, 1401/12/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Examining the effect of Curcumin on fasting blood sugar and insulin resistance index in prediabetic individuals

Public title

Investigating the effect of Curcumin on prediabetic individuals

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Individuals aged 18-70 years Prediabetes status

Satisfaction for participation in research project

Exclusion criteria:

Using anti diabetic drugs or other drugs which affect on

blood sugar such as Thiazide, Glucocorticoids, Anti-

psychotics Systemic disorders such as hepatic or renal

failure Oral intolerance Using anti-coagulant drugs

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **56**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization was done using the block sizes of 4 and 6 with randomization websites such as sealedenvelope.com. After randomization, the type of treatment is written with odds and even numbers (or A/B codes) in separate papers and placed in an opaque envelope or the paper will wrap so that no one can see inside the paper (random concealment). After obtaining informed consent from the participants, one paper will be taken in order and according to the noted code, the child is place in one of the intervention or placebo groups

Blinding (investigator's opinion)

Triple blinded

Blinding description

As mentioned before, after randomization, the patients place in two groups of A/B (or odds/even codes) and received the products similar in shape, color and size (blinding of participants). The physician who will give the products to participants, received the boxes of the products with randomized codes (so the physician is blind too). The information of the patients and theirs treatment groups will be written with randomized codes (A/B) (the blinding of the assessor). Data will be entered to the SPSS software with codes (the blinding of the analyzer).

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine,
Mashhad University of Medical Sciences

Street address

Faculty of Medicine, University Campus, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2022-12-20, 1401/09/29

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1401.593

Health conditions studied

1

Description of health condition studied

Prediabetes

ICD-10 code

R73.0

ICD-10 code description

Abnormal glucose tolerance test

Primary outcomes

1

Description

FBS (Fasting Blood Sugar)

Timepoint

Baseline and after 3 months.

Method of measurement

Blood sample

2

Description

HOMA-IR (Homeostatic Model Assessment for Insulin
Resistance)

Timepoint

Baseline and after 3 months

Method of measurement

Using formula: (Glucose * insulin)/405

Secondary outcomes

1

Description

CRP, HbA1C, Insulin

Timepoint

Baseline and after 3 months

Method of measurement

Blood sample

Intervention groups**1****Description**

Intervention group: Curcumin tablet daily (contains 500 mg Curcumin and 5 mg Piperine)

Category

Treatment - Drugs

2**Description**

Control group: placebo (similar to intervention in shape, size and color)

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Endocrinology Clinic.

Full name of responsible person

Zahra Mazloun Khorasani

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Between Moallem 8th and 10, Moallem Blvd, Mashhad

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Maryam Emadzadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Public Health/Community Medicine

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Zahra Mazloun khorasani

Position

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Latest degree

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Other areas of specialty/work

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Position

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Latest degree

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Other areas of specialty/work

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Mashhad

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be 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

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

Data Dictionary

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