

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparison of curcumin's effects in simple and modified formulations on cardiovascular risk factors in patients with metabolic syndrome

Protocol summary

Summary

The best of our aim is the comparison of curcumin's effects in simple and modified formulations on cardiovascular risk factors in patients with metabolic syndrome. This study will be conducted on 120 metabolic syndrome patients aged 18–65 years who not having any history of systemic disease. A diagnosis of Metabolic syndrome was based on the IDF criteria : Abdominal obesity (waist circumference >94 cm for men and >80 cm for women), or an elevated BMI + 2 of the following: Triglycerides \geq 150 mg/dl, HDL-C< 40 mg/dl in men and <50 mg/dl in women, Blood pressure \geq 130/85 mmHg, Fasting glucose \geq 100 mg/dl. Subjects who are indicated for pharmacologic intervention according to the American Heart Association guidelines will be omitted from the study. Recruited patients will be randomly assigned to 3 groups receiving simple and modified curcumin (1 g/day) and placebo capsules for a period of 6 weeks. Each patient will have the same diet and visit once during drug consumption. Anthropometric indices, blood pressure and demographic information will be documented. CBC and lipids profile will be measured for everyone before and after intervention. The serum concentrations of interleukin-1 α -1 β -6 and TNF- α will be detected using Enzyme-Linked Immunosorbent Assay (ELISA). Our results can help determining the clinical benefits of supplementation with curcumin in patients with metabolic syndrome.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014052014521N3**

Registration date: **2014-08-11, 1393/05/20**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-08-11, 1393/05/20

Registrant information

Name

Amirhossein Sahebkar

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1882 9260

Email address

sahebkar@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Research Vice Chancellor of Mashhad University of Medical Sciences

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2014-11-22, 1393/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of curcumin's effects in simple and modified formulations on cardiovascular risk factors in patients with metabolic syndrome

Public title

Comparison of curcumin's effects in simple and modified formulations in patients with metabolic syndrome

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria : Men and women aged 18-65 years ; Metabolic Syndrome patients (based on IDF guidelines) ; Consent to participate in research project ; Not taking any dietary supplement ; Not taking any drugs within the last 3-6 months (Not history of taking any lipid-lowering, diabetes and hypertension drugs or insulin within the last 3-6 months) . Exclusion criteria : Lack of informed consent of patient to participate in research project ; Having systemic disease or history of systemic disease (such as lupus and kidney disease) ; Not having Metabolic Syndrome ; Pregnancy or lactation ; Consumption of any drug supplement or lipid-lowering drug within the last 3-6 months ; Metabolic syndrome subjects who need to take any drug (based on American Heart Association guidelines) .

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Daneshgah Street

City

Mashhad

Postal code

۳۴۵ - ۹۱۳۷۵

Approval date

2014-01-20, 1392/10/30

Ethics committee reference number

921312

Health conditions studied

1

Description of health condition studied

Obesity

ICD-10 code

E66

ICD-10 code description

Obesity

2

Description of health condition studied

Non-insulin-dependent diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

3

Description of health condition studied

hypertriglyceridaemia

ICD-10 code

E78.1

ICD-10 code description

Pure hyperglyceridaemia

4

Description of health condition studied

hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

5

Description of health condition studied

High-density lipoprotein deficiency

ICD-10 code

E78.6

ICD-10 code description

Lipoprotein deficiency

Primary outcomes

1

Description

Triglycerides

Timepoint

Baseline, week 6

Method of measurement

Routine enzymatic methods using standard biochemistry kits on an autanalyzer

Secondary outcomes

1

Description

Apo B

Timepoint

Baseline, week 6

Method of measurement

ELISA

2

Description

Apo A

Timepoint

Baseline, week 6

Method of measurement

ELISA

3

Description

Adiponectin

Timepoint

Baseline, week 6

Method of measurement

ELISA

4

Description

CETP

Timepoint

Baseline, week 6

Method of measurement

ELISA

5

Description

HS-CRP

Timepoint

Baseline, week 6

Method of measurement

immunoturbidimetric assay

6

Description

Lp (a)

Timepoint

Baseline, week 6

Method of measurement

ELISA

7

Description

CBC

Timepoint

Baseline, week 6

Method of measurement

Sysmex KX-21 Hematology Analyzer

8

Description

Total cholesterol

Timepoint

Baseline, week 6

Method of measurement

Routine enzymatic methods using standard biochemistry kits on an autanalyzer

9

Description

HDL-c

Timepoint

Baseline, week 6

Method of measurement

Routine enzymatic methods using standard biochemistry kits on an autanalyzer

10

Description

LDL-c

Timepoint

Baseline, week 6

Method of measurement

Routine enzymatic methods using standard biochemistry kits on an autanalyzer

11

Description

Prooxidant-antioxidant balance

Timepoint

Baseline, week 6

Method of measurement

Colorimetric assay

12

Description

PON

Timepoint

Baseline, week 6

Method of measurement

ELISA

13

Description

Anti- HSP27

Timepoint

Baseline, week 6

Method of measurement

ELISA

14

Description

interleukin-1 β (IL-1 β)

Timepoint

Baseline, week 6

Method of measurement

biochip array immunoassay

15

Description

interleukin-1 α (IL-1 α)

Timepoint

Baseline, week 6

Method of measurement

biochip array immunoassay

16

Description

interleukin-6 (IL-6)

Timepoint

Baseline, week 6

Method of measurement

biochip array immunoassay

17

Description

tumor necrosis factor (TNF- α)

Timepoint

Baseline, week 6

Method of measurement

biochip array immunoassay

18

Description

Intercellular Adhesion Molecule-1 (ICAM-1),

Timepoint

Baseline, week 6

Method of measurement

ELISA

19

Description

L-Selectin

Timepoint

Baseline, week 6

Method of measurement

ELISA

20

Description

Anxiety

Timepoint

Baseline, week 6

Method of measurement

Questionnaire

21

Description

Depression

Timepoint

Baseline, week 6

Method of measurement

Questionnaire

22

Description

Vascular Cell Adhesion Molecule-1 (VCAM-1)

Timepoint

Baseline, week 6

Method of measurement

ELISA

Intervention groups

1

Description

Simple Curcumin (unformulated)

Category

Treatment - Drugs

2

Description

Control group: placebo for 6 weeks

Category

Placebo

3

Description

Curcumin-phospholipid complex

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Dr. Majid Ghayour Mobarhan

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

dr Mohsen Tafaghodi

Street address

Pharmaceutical Chemistry Department , School of Pharmacy , Vakilabad blvd

City

Mashhad

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

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

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Amirhossein Sahebkar

Position

PhD. (Pharmaceutical Biotechnology)

Other areas of specialty/work**Street address**

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty