Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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≥ 150 mg/dl, HDL-C< 40 mg/dl in men and <50 mg/dl in women, Blood pressure≥ 130/85 mmHg, Fasting glucose≥ 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-1α/-1β/-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
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Iran (Islamic Republic of)
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+98 51 1882 9260
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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 autonalyzer

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 autonalyzer

9

Description
HDL-c
Timepoint
Baseline, week 6
Method of measurement
Routine enzymatic methods using standard biochemistry kits on an autonalyzer

10

Description
LDL-c
Timepoint
Baseline, week 6
Method of measurement
Routine enzymatic methods using standard biochemistry kits on an autonalyzer

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-1β (IL-1β)
Timepoint
Baseline, week 6
Method of measurement

biochip array immunoassay

15

Description
interleukin-1α (IL-1α)
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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
dr Mohsen Tafaghodi
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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

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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