# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Investigation of the effects of supplementation with curcuminoids on on cardiovascular risk factors in obese dyslipidemic subjects

## Protocol summary

**Summary**
Dyslipidemia is a leading risk factor for cardiovascular disease and is also a common feature of obesity. Curcumin is a bioactive phytochemical with well-known antioxidant, anti-inflammatory and cardioprotective properties. The present study investigated the clinical efficacy of of curcumin in obese individuals. Participants (n = 30) were treated with curcuminoids (1 g/day), or placebo for a period of 4 weeks each (intermitted by a two-week wash-out phase) in a randomized, double-blind, placebo-controlled, cross-over trial.

## General information

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT2013082914521N1**
Registration date: **2013-09-14, 1392/06/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**
2013-09-14, 1392/06/23

**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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**Recruitment status**
**Recruitment complete**

**Funding source**
Mashhad University of Medical Sciences

**Expected recruitment start date**
2010-08-21, 1389/05/30
**Expected recruitment end date**
2012-08-20, 1391/05/30
**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
Investigation of the effects of supplementation with curcuminoids on on cardiovascular risk factors in obese dyslipidemic subjects

**Public title**
Investigation of the effects of curcuminoids on the risk of heart disease
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
Inclusion criteria: obese subjects (with body mass index (BMI) ≥ 30) who had either < 2 risk factors (except diabetes mellitus) for coronary heart disease (CHD) plus 160 mg/dL < LDL-C < 190 mg/dL, or ≥ 2 CHD risk factors (except diabetes mellitus) and 130 mg/dL < LDL-C < 160 mg/dL. Exclusion criteria were history of systemic diseases (such as systemic lupus erythematosus, kidney disease, diabetes mellitus and established cardiovascular disease), consumption of drug supplements within the preceding 6 months and history of taking any lipid-lowering drug. Exclusion criteria: systemic disease or history of systemic disease (such as lupus, kidney disease, diabetes mellitus); history of cardiovascular disease; BMI < 30; consumption of drug supplements within the 6 months and history of taking any lipid lowering drug.

**Age**
From **18 years** old to **65 years** old
**Gender**
Both

**Phase**
2
**Groups that have been masked**
*No information*
**Sample size**
Target sample size: **30**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
**Placebo**
Used
**Assignment**
Crossover
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Mashhad University of Medical Sciences
**Street address**
Daneshgah st., PO Box: 91375-345
**City**
Mashhad
**Postal code**
9177899191
**Approval date**
2010-05-12, 1389/02/22
**Ethics committee reference number**
88313

## Health conditions studied

### 1

**Description of health condition studied**
Dyslipidemia
**ICD-10 code**
**ICD-10 code description**

### 2

**Description of health condition studied**
Obesity
**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

### 1

**Description**
Total cholesterol
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Routine enzymatic methods using standard biochemistry kits on an autonalyzer

### 2

**Description**
Triglycerides
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Routine enzymatic methods using standard biochemistry kits on an autonalyzer

### 3

**Description**
HDL cholesterol
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Routine enzymatic methods using standard biochemistry kits on an autonalyzer

### 4

**Description**
LDL cholesterol
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Routine enzymatic methods using standard biochemistry kits on an autonalyzer

## Secondary outcomes

### 1

**Description**
vitamin C, vitamin E, lipoprotein(a) and cathepsin D
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Questionnaire, enzymatic and immunoassay kits

### 2

**Description**
Anxiety
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Questionnaire

### 3

**Description**
Serum small dense LDL
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Enzyme immunoassay

### 4

**Description**
Heat shock protein 27 antibodies
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Enzyme immunoassay

### 5

**Description**
Pro-oxidan-antioxidant blance
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Colorimetric assay

### 6

**Description**
Cytokines
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Enzyme immunoassay

### 7

**Description**
Superoxide dismutase
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Enzymatic assay

### 8

**Description**
Zinc
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Enzymatic assay

### 9

**Description**
Copper
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Enzymatic assay

### 10

**Description**
Vitamins
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Enzymatic assay

### 11

**Description**
Lipoprotein(a)
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Enzyme immunoassay

### 12

**Description**
Cathepsin D
**Timepoint**
Baseline, week 4, week 6 and week 10
**Method of measurement**
Enzyme immunoassay

## Intervention groups

### 1

**Description**
Curcuminoids are bioactive ingredients of turmeric. They belong to the polyphenol group of phytochemicals. The chemical name of curcumin is (1E,6E)-1,7-Bis(4-hydroxy-3-methoxyphenyl)-1,6-heptadiene-3,5-dione. In the present trial curcumin would be administered b.i.d in two divided doses of 500 mg.
**Category**
Treatment - Drugs

### 2

**Description**
Control group: placebo for 4 weeks
**Category**
Placebo

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Ghaem Hospital
**Full name of responsible person**
**Street address**
**City**
Mashhad

## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
Mashhad University of Medical Sciences Research Council

**Full name of responsible person**
Dr. Mohsen Tafaghodi

**Street address**
Daneshgah st.

**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 Research Council

**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**
Cardiovascular Research Center, Mashhad University of Medical Sciences

**Full name of responsible person**
Majid Ghayour-Mobarhan

**Position**
Associate Professor, MD, PhD

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

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Associate Professor/MD-PhD

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## Person responsible for updating data

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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*