

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Aug 2026

### Investigation of the effects of supplementation with curcuminoids 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 curcumin in obese individuals. Participants (n = 30) were treated with curcuminoids (1 g/day), or placebo for a period of 4 weeks each (intermittent 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 1882 9260

###### Email address

sahebkar@mums.ac.ir

##### 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 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)  $\geq 30$ ) who had either  $< 2$  risk factors (except diabetes mellitus) for coronary heart disease (CHD) plus  $160 \text{ mg/dL} < \text{LDL-C} < 190 \text{ mg/dL}$ , or  $\geq 2$  CHD risk factors (except diabetes mellitus) and  $130 \text{ mg/dL} < \text{LDL-C} < 160 \text{ mg/dL}$ . 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 autanalyzer

### 2

#### Description

Triglycerides

#### Timepoint

Baseline, week 4, week 6 and week 10

#### Method of measurement

Routine enzymatic methods using standard biochemistry kits on an autanalyzer

### 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 autanalyzer

### 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 autanalyzer

## 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-oxidant-antioxidant balance

**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**

#### **Street address**

School of Medicine, Vakilabad blvd.

#### **City**

Mashhad

#### **Postal code**

#### **Phone**

+98 51 1882 9260

#### **Fax**

#### **Email**

ghayourm@mums.ac.ir

#### **Web page address**

## **Person responsible for scientific inquiries**

### **Contact**

### **Name of organization / entity**

Cardiovascular Research Center, Mashhad University of Medical Sciences

### **Full name of responsible person**

Dr. Majid Ghayour-Mobarhan

### **Position**

Associate Professor/MD-PhD

### **Other areas of specialty/work**

### **Street address**

School of Medicine, Vakilabad blvd.

### **City**

Mashhad

### **Postal code**

### **Phone**

+98 51 1882 9260

### **Fax**

### **Email**

ghayourm@mums.ac.ir

### **Web page address**

## **Person responsible for updating data**

### **Contact**

#### **Name of organization / entity**

Cardiovascular Research Center, Mashhad University of Medical Sciences

#### **Full name of responsible person**

Dr. Majid Ghayour-Mobarhan

#### **Position**

MD-PhD

#### **Other areas of specialty/work**

#### **Street address**

School of Medicine

#### **City**

Mashhad

#### **Postal code**

#### **Phone**

+98 51 1882 9260

#### **Fax**

#### **Email**

ghayourm@mums.ac.ir

#### **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*