

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Effect of Nano-curcumin versus not receiving it on serum levels of Betatrophin and Irisin in patients with metabolic syndrome: a before-after clinical trial

#### Protocol summary

##### Study aim

To assess the effect of Nano-curcumin versus not receiving it on serum levels of Betatrophin and Irisin in patients with metabolic syndrome

##### Design

This a before-after clinical trial, phase II, in which 60 eligible patients will receive intervention and will be compared with before intervention

##### Settings and conduct

The eligible patients with metabolic syndrome who will refer to Shahid Beheshti Hospital during the study period will be enrolled in the trial

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 70 years Metabolic syndrome Exclusion criteria: Diabetes Thyroid disease Liver disease Renal disease Using interfering drugs with carbohydrate and lipid metabolism

##### Intervention groups

Intervention group: Nano-curcumin tablet 80 mg daily for 2 months Control group: In comparison with before intervention

##### Main outcome variables

Primary outcome: measuring the serum levels of Betatrophin before intervention and 2 months later through the laboratory test; measuring the serum levels of Irisin before intervention and 2 months later through the laboratory test.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120215009014N214**

Registration date: **2018-03-19, 1396/12/28**

Registration timing: **prospective**

Last update: **2018-03-19, 1396/12/28**

Update count: **0**

##### Registration date

2018-03-19, 1396/12/28

##### Registrant information

###### Name

Jalal Poorolajal

###### Name of organization / entity

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 81 1838 0090

###### Email address

poorolajal@umsha.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2018-04-08, 1397/01/19

##### Expected recruitment end date

2019-01-09, 1397/10/19

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of Nano-curcumin versus not receiving it on serum levels of Betatrophin and Irisin in patients with metabolic syndrome: a before-after clinical trial

##### Public title

Effect of Nano-curcumin versus not receiving it on serum

levels of Betatrophin and Irisin in patients with metabolic syndrome

### **Purpose**

Treatment

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

Age: 18 to 70 years old Metabolic syndrome diagnosis

#### **Exclusion criteria:**

Diabetes Thyroid disease Liver disease Renal disease  
Using interfering drugs with carbohydrate and lipid metabolism

### **Age**

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

### **Gender**

Both

### **Phase**

2

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **60**

### **Randomization (investigator's opinion)**

N/A

### **Randomization description**

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Not used

### **Assignment**

Single

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics Committee of Hamadan University of Medical Sciences

##### **Street address**

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave

##### **City**

Hamadan

##### **Province**

Hamadan

##### **Postal code**

6517838695

#### **Approval date**

2018-03-10, 1396/12/19

#### **Ethics committee reference number**

IR.UMSHA.REC.1396.859

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Metabolic syndrome

#### **ICD-10 code**

E88.81

#### **ICD-10 code description**

Metabolic syndrome

## **Primary outcomes**

### 1

#### **Description**

Measuring the serum levels of Betatrophin

#### **Timepoint**

Before intervention and 2 months later

#### **Method of measurement**

Through the laboratory test

### 2

#### **Description**

Measuring the serum levels of Irisin

#### **Timepoint**

Before intervention and 2 months later

#### **Method of measurement**

Through the laboratory test

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Nano-curcumin tablet 80 mg daily for 2 months

#### **Category**

Treatment - Drugs

### 2

#### **Description**

#### **Category**

N/A

## **Recruitment centers**

### 1

#### **Recruitment center**

##### **Name of recruitment center**

Shahid Beheshti Hospital

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

Zahra Khodamoradi

##### **Street address**

Shahid Beheshti Hospital, Eram Ave.

**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0283  
**Email**  
khodamoradzahra@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr Saeid Bashirian  
**Street address**  
Hamadan University of Medical Sciences, Shahid  
Fahmideh Ave  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0717  
**Email**  
info.research@umsha.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Hamedan 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**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Zahra Khodamoradi  
**Position**  
Medical Student  
**Latest degree**

Medical doctor  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
Shahid Beheshti Hospital, Eram Ave.  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0283  
**Email**  
khodamoradzahra@gmail.com

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Shiva Bozooei  
**Position**  
Endocrinologist  
**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Shahid Beheshti Hospital, Eram Ave.  
**City**  
Hamadan  
**Province**  
Hamadan  
**Postal code**  
6517838695  
**Phone**  
+98 81 3838 0283  
**Email**  
borzooeishiva@yahoo.com

## Person responsible for updating data

#### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr Jalal Poorolajal  
**Position**  
Professor of Epidemiology  
**Latest degree**  
Ph.D.  
**Other areas of specialty/work**  
Epidemiology  
**Street address**  
School of Public Health, Hamadan University of  
Medical Sciences, Shahid Fahmideh Ave  
**City**  
Hamadan  
**Province**

Hamadan

**Postal code**

6517838695

**Phone**

+98 81 3838 0090

**Email**

poorolajal@umsha.ac.ir

## 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