

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 2026

### The Effect of Curcumin Supplementation as Nano-micelles and Low Calorie- Low Glycemic Index Diet Education on Metabolic Syndrome Indices in patients referred to Taleghani Hospital diabetes clinic

#### Protocol summary

##### Summary

Determining the Effect of Receiving the Curcumin Supplement as Nano-Micelles and Educating Low Calorie- Low Glycemic Index Diet on Metabolic Syndrome Indices. The study will be conducted as a Double-Blind Randomized Controlled Trial with the standard placebo. The required sample size for the study, considering the 20% probability of subject missing, will be 45 subjects for each groups and 90 subjects in total. All the subjects will be taught low calorie- low glycemic index diet, then subjects randomly will be divided to the two groups of receiving Curcumin or placebo. All of the procedures will be conducted double- blind to the researcher and patients alike and also in supervision of a third person. The intervention will be done for 12 weeks. Regarding the results of previous human studies conducted on Curcumin, consumption of these capsules will not have any side effect for patients. Patients who have at least 3 criteria of all of 5 criteria of Metabolic Syndrome provided that not taking medicine for controlling Blood Glucose, Blood Lipid and Hypertension will be included to the study. In case of losing any of including criteria or having to taking any of aforementioned medications will be excluded from the study. The main outcomes expected to be applied by the interventions, will be include: increase in High-Density Lipoprotein- Cholesterol (HDL-C) and reduce Triglycerides, Blood Pressure, Waist Circumference and Blood Glucose.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021326530N1**

Registration date: **2016-05-21, 1395/03/01**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2016-05-21, 1395/03/01

##### Registrant information

###### Name

Soheil Abbasi

###### Name of organization / entity

Kermanshah University of Medical Science, Public Health Faculty

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 3828 1991

###### Email address

s.abbasi@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice - Chancellery of Research & Technology Affairs, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2016-06-04, 1395/03/15

##### Expected recruitment end date

2016-07-20, 1395/04/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of Curcumin Supplementation as Nano-micelles and Low Calorie- Low Glycemic Index Diet Education on Metabolic Syndrome Indices in patients referred to Taleghani Hospital diabetes clinic

**Public title**

Therapeutic Effects of Curcumin as Supplement on Metabolic Syndrome

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

The main including criteria: Filling the consent form of the present project in the beginning of study; lack of any kinds of chronic diseases such as diabetes, renal diseases, tuberculosis, liver diseases and/or the history of cardiac surgery; possessing at least 3 items of all the 5 indexes of metabolic syndrome (based on the definition by NCEP ATP III) (in case of insulin resistance, patients must have fasting blood glucose less than 126 mg/dL, otherwise these patients diagnosed as diabetic patients and must have exclude from the study); lack of taking medicine to control blood glucose, blood lipid and hypertension; the age range between 25 to 65 year; lack of injecting insulin so as to blood glucose control. The main exclusion criteria: Lack of regular taking the given supplements; lack of following the given diet which evaluated by the analysis of 3 days recall questionnaire by using Nutritionist- 4 software; starting taking medicine or supplements that may be affect the results of test of investigated factors or oral contraceptives, estrogen, progesterone and corticosteroids; pregnancy; taking/receiving insulin or tablet to control the blood glucose; losing any of inclusion criteria during the time of conducting the study.

**Age**

From **24 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **90**

**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**

Kermanshah University of Medical Sciences Ethics

Committee

**Street address**

Deputy of Research and Technology, Building No. 2 of Kermanshah University of Medical Science, Naft Square, Shahid Beheshti blvd.

**City**

Kermanshah

**Postal code****Approval date**

2016-04-23, 1395/02/04

**Ethics committee reference number**

kums.rec.1395.4

**Health conditions studied****1****Description of health condition studied**

Hypertension

**ICD-10 code**

I15.9

**ICD-10 code description**

Secondary hypertension, unspecified

**2****Description of health condition studied**

Hyperglyceridaemia

**ICD-10 code**

E78.1

**ICD-10 code description**

Pure hyperglyceridaemia

**3****Description of health condition studied**

Prediabetic

**ICD-10 code**

R73.0

**ICD-10 code description**

Abnormal glucose tolerance test

**4****Description of health condition studied**

low HDL-C

**ICD-10 code**

E78.6

**ICD-10 code description**

High-density lipoprotein deficiency

**Primary outcomes****1****Description**

plasma Glucose

**Timepoint**

base line and aftar 3 months of begin

**Method of measurement**

in term of mg/ dL by biochemical kits

## 2

### **Description**

blood pressure

### **Timepoint**

base line, at the end of 6th week and after 3 months of begin

### **Method of measurement**

in term of mm Hg by Mercury barometers

## 3

### **Description**

plasma HDL-C

### **Timepoint**

base line and after 3 months of begin

### **Method of measurement**

in term of mg/ dL by biochemical kits

## 4

### **Description**

plasma TG

### **Timepoint**

base line and after 3 months of begin

### **Method of measurement**

in term of mg/ dL by biochemical kits

## 5

### **Description**

Waist Circumference

### **Timepoint**

base line, at the end of 6th week and after 3 months of begin

### **Method of measurement**

in term of centimeter by Tape measure

## **Secondary outcomes**

## 1

### **Description**

Total Cholesterol

### **Timepoint**

baseline and after 3th month

### **Method of measurement**

in term of mg/ dL, by using biochemical kits

## 2

### **Description**

LDL-C

### **Timepoint**

baseline and after 3th month

### **Method of measurement**

in term of mg/ dL, by using biochemical kits

## 3

### **Description**

Body Fat Mass

### **Timepoint**

baseline, at the end of 6th week and after 3th month

### **Method of measurement**

in term of kg, by usig body analyser instrument

## 4

### **Description**

Body Fat Free Mass

### **Timepoint**

baseline, at the end of 6th week and after 3th month

### **Method of measurement**

in term of kg, by usig body analyser instrument

## 5

### **Description**

Body Mass Index (BMI)

### **Timepoint**

baseline, at the end of 6th week and after 3th month

### **Method of measurement**

in term of kg/ m<sup>2</sup>

## 6

### **Description**

weight

### **Timepoint**

baseline, at the end of 6th week and after 3th month

### **Method of measurement**

in term of kg by using standardized scale

## **Intervention groups**

## 1

### **Description**

for intervention group: Curcumin Dietary Supplement, 40 mg soft gel, twice/ day by oral, for 3 months

### **Category**

Treatment - Drugs

## 2

### **Description**

for intervention and control groups: training low calorie-low glycemic index diet. for all participants, this training will be taught in baseline and in the end of 6th week.

### **Category**

Lifestyle

## 3

### **Description**

for control group: Standardized Placebo, quite similar to Curcumin soft gels, twice/ day, for 3 months by oral

### **Category**

Placebo

## **Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Diabetes Clinic of Taleqani Hospital

**Full name of responsible person**

Secretary of clinic

**Street address**

Diabetes Clinic, Taleqani Hospital, Naft Square,  
Shahid Beheshti blvd

**City**

Kermanshah

Dovlat Ababd blvd, Isar Square, Imam Hosein Exp

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6719851351

**Phone**

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**Email**

s.abbasi@kums.ac.ir; yahya.pasdar@kums.ac.ir

**Web page address**

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Vice - Chancellery of Research & Technology Affairs  
of Kermanshah University of Medical Sciences

**Full name of responsible person**

Kourosh Hamzehee

**Street address**

Vice- Chancellery of Research & Technology Affairs,  
Building No. 2 of Kermanshah University of Medical  
Science, Naft Square, Shahid Beheshti blvd

**City**

Kermanshah

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

Vice - Chancellery of Research & Technology Affairs of  
Kermanshah 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**

Public Health faculty of Kermanshah University of  
Medical Science

**Full name of responsible person**

Soheil Abbasi

**Position**

MSc student in Nutrition Science/ Executor of plan

**Other areas of specialty/work**

**Street address**

Public Health faculty, Next to the Farabi Hospital,

**Person responsible for scientific  
inquiries**

**Contact**

**Name of organization / entity**

Public Health faculty of Kermanshah University of  
Medical Science

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**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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**Fax**

**Email**

s.abbasi@kums.ac.ir; yahya.pasdar@kums.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*