

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jun 2026

### Assessment of the effect of Acarbose on anthropometric indices and metabolic markers in obese women with metabolic syndrome

#### Protocol summary

##### Study aim

Assessment of effect of Acarbose and placebo on the Anthropometric Indicators and metabolic markers in obese women with metabolic syndrome

##### Design

30 patient with BMI = 30 or more than 30 and metabolic syndrome for treatment with Acarbose and 30 patient for treatment with placebo. The patients accidentally divided to 2 groups.

##### Settings and conduct

People with BMI more than 30 enrolled in this study and give them 300 mg tablet of Acarbose. Before and after intervention we check demographic information and metabolic markers. Then we analyzed data.

##### Participants/Inclusion and exclusion criteria

Entry requirement to study: people, metabolic syndrome, age between 20\_50, BMI = 30 or more than 30  
Conditions for not admitting to study: chronic disease beside metabolic syndrome, lack of cooperation, lipid lowering drug consumer, Metformin consumer in past year, weight loss or diet in past year

##### Intervention groups

We give by random acarbose or placebo to two groups of people who participate in study

##### Main outcome variables

Assessment of the efficacy of Acarbose on waist circumference and LDL, AST, ALT, cholesterol  
Echocardiography, ..

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20130924014752N5**

Registration date: **2018-03-05, 1396/12/14**

Registration timing: **retrospective**

Last update: **2018-03-05, 1396/12/14**

Update count: **0**

##### Registration date

2018-03-05, 1396/12/14

##### Registrant information

###### Name

Noushin Khalili boroujeni

###### Name of organization / entity

Isfahan university of medical science

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 1792 2472

###### Email address

n\_khalili@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-03-01, 1395/12/11

##### Expected recruitment end date

2018-02-20, 1396/12/01

##### Actual recruitment start date

2017-03-01, 1395/12/11

##### Actual recruitment end date

2018-02-20, 1396/12/01

##### Trial completion date

empty

##### Scientific title

Assessment of the effect of Acarbose on anthropometric indices and metabolic markers in obese women with metabolic syndrome

##### Public title

Acarbose effect in metabolic syndrome

##### Purpose

Prevention

##### Inclusion/Exclusion criteria

**Inclusion criteria:**

BMI=30 or more than 30 Affected by metabolic syndrome Female Age between 20\_50 years

**Exclusion criteria:**

Chronic disease beside metabolic syndrome Non cooperative Consuming anti Lipid drugs Consuming Metformin in past year Weight loss or diet in past year

**Age**

From **20 years** old to **50 years** old

**Gender**

Female

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor

**Sample size**

Target sample size: **80**

Actual sample size reached: **78**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

People who

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

One of our colleagues is selected to attach a blue or green tag on drug or placebo boxes. Only two people know about the meaning of color .If participant has any adverse ,they refer to this colleague who knows about placebo or drug administration and he decide to continue or finish study.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Isfahan University of Medical sciences

**Street address**

HezarJerib Street

**City**

Isfahan

**Province**

Isfahan

**Postal code**

8174673461

**Approval date**

2016-11-22, 1395/09/02

**Ethics committee reference number**

IR.MUI.REC.1395.4.060

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

Obesity

**ICD-10 code**

E66

**ICD-10 code description**

Overweight and obesity

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

Body weight

**Timepoint**

At the first visit and each two weeks after three month of consumption of total dose of drug or dose of patient tolerance.

**Method of measurement**

Body weight scales

**2****Description**

Height

**Timepoint**

At first visit and last visit

**Method of measurement**

Height gauge

**3****Description**

waist

**Timepoint**

At first visit and last visit

**Method of measurement**

Strip meter

**4****Description**

fasting blood suger

**Timepoint**

At first visit and end of study

**Method of measurement**

Enzymatic lab study

**5****Description**

insulin level of serum

**Timepoint**

At first visit and end of study

**Method of measurement**

ELISA method

## 6

### **Description**

Epicardial fat thickness

### **Timepoint**

At first visit and end of study

### **Method of measurement**

Echocardiography

## 7

### **Description**

Body Mass Index (BMI)

### **Timepoint**

At first visit and end of study

### **Method of measurement**

BMI = kg/m<sup>2</sup> person's weight in kilograms and m<sup>2</sup> is their height in metres squared

## **Secondary outcomes**

### 1

#### **Description**

flatulence

#### **Timepoint**

Each two weeks

#### **Method of measurement**

Questioner

## **Intervention groups**

### 1

#### **Description**

Intervention group: acarbose is administrated for three month with 300 mg .At first it is prescribed with low dose 25 mg three times a day, and gradually placebo dose is increased till 100 mg for each meal.

#### **Category**

Treatment - Drugs

### 2

#### **Description**

Control group: placebo is administrated for three month with 300 mg daily .the dose of placebo is increased gradually from 25 mg to 100mg three times for each meal .

#### **Category**

Placebo

## **Recruitment centers**

### 1

#### **Recruitment center**

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

Endocrine Research Center of Isfahan University of Medical Science

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

Dr Noushin Khalili

#### **Street address**

Khoram Street

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8187698191

#### **Phone**

+98 31 3335 9090

#### **Email**

n\_khalili@med.mui.ac.ir

## **Sponsors / Funding sources**

### 1

#### **Sponsor**

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

Endocrine Research Center of Isfahan University of Medical Science

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

Dr Ashraf Aminoroaya

##### **Street address**

KHORAM STREET

##### **City**

ISFAHAN

##### **Province**

Isfahan

##### **Postal code**

8187698191

##### **Phone**

+98 31 3355 9090

##### **Email**

n\_khalili@med.mui.ac.ir

##### **Web page address**

##### **Grant name**

##### **Grant code / Reference number**

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

Yes

##### **Title of funding source**

Endocrine Research Center of Isfahan University of Medical Science

##### **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**

Esfahan University of Medical Sciences  
**Full name of responsible person**  
Dr Noushin Khalili  
**Position**  
Assistante Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Khoram Street  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8187698191  
**Phone**  
+98 31 3335 9090  
**Email**  
n\_khalili@med.mui.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences  
**Full name of responsible person**  
Khalili Noushin  
**Position**  
Assistant Professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Khoram Street  
**City**  
Isfahan  
**Province**  
Isfahan  
**Postal code**  
8187698191  
**Phone**  
+98 31 3335 9090  
**Email**  
n\_khalili@med.mui.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Esfahan University of Medical Sciences

**Full name of responsible person**  
Khalili Noushin  
**Position**  
Assistant professor  
**Latest degree**  
Subspecialist  
**Other areas of specialty/work**  
Internal Medicine  
**Street address**  
Khoram Street  
**City**  
isfahan  
**Province**  
Isfahan  
**Postal code**  
8187698191  
**Phone**  
+98 31 3335 9090  
**Email**  
n\_khalili@med.mui.ac.ir

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### Study Protocol

Yes - There is a plan to make this available

### Statistical Analysis Plan

Yes - There is a plan to make this available

### Informed Consent Form

Yes - There is a plan to make this available

### Clinical Study Report

Yes - There is a plan to make this available

### Analytic Code

Yes - There is a plan to make this available

### Data Dictionary

Yes - There is a plan to make this available

### Title and more details about the data/document

we will publish all kind of information about our study

### When the data will become available and for how long

after published it is available for all to get it

### To whom data/document is available

researcher and academic people and people who enrolled in study

### Under which criteria data/document could be used

for improvement of health care and treatment

### From where data/document is obtainable

we will publish it in academic journal then others can use it

### What processes are involved for a request to access data/document

the academic person can email to author to get it

### Comments