# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

16 Sep 2026

## Comparison of the effect of low glycemic index diet and metformin drug on metabolic syndrome components in adults with metabolic syndrome

## Protocol summary

**Summary**

Metabolic syndrome continues to be highly prevalent and contributes to a rapidly growing problem globally. The most important therapeutic intervention is diet modification; an intervention that its efficacy has been proven in metabolic syndrome. Some studies have shown that low glycemic index diet has positive effects on patients with MetS. So, the goal of this study is to compare the effects of low Glycemic Index diet and metformin drug on MetS components in order to replace the drug by the diet in adults with MetS. This study is a Randomised Controlled Clinical Trial. The inclusion criteria are the age between 25 and 65 years old and having 3 characteristics related to metabolic syndrome according to the Adult Treatment Panel, not taking any drug that might affect blood pressure and glucose, insulin or lipid metabolism, not having diabetes, liver or kidney diseases. Patients will be excluded if they get gastrointestinal disorders or lose their interest to continue the study. The 60 patients will be randomly allocated to two groups of metformin drug and low Glycemic Index diet. The intervention period is 8 weeks and at the end of the trial, the groups will be compared regarding the following factors: weight , blood pressure , waist circumference, fasting blood sugar and lipid profiles (TG, total cholesterol, LDL, HDL).

## General information

**Acronym**

**IRCT registration information**

IRCT registration number: **IRCT2013052013399N1**
Registration date: **2014-03-02, 1392/12/11**
Registration timing: **retrospective**

Last update:
Update count: **0**

**Registration date**

2014-03-02, 1392/12/11

**Registrant information**

**Name**
Shirin Rajabi
**Name of organization / entity**
Shiraz University of Medical Sciences
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Iran (Islamic Republic of)
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**Recruitment status**

**Recruitment complete**

**Funding source**
Shiraz University of Medical Sciences

**Expected recruitment start date**
2013-08-24, 1392/06/02

**Expected recruitment end date**
2014-02-19, 1392/11/30

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**

Comparison of the effect of low glycemic index diet and metformin drug on metabolic syndrome components in adults with metabolic syndrome

**Public title**

The effect of metformin and diet on metabolic syndrome treatment

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Having 3 characteristics related to

metabolic syndrome according to ATPIII ( Adult Treatment Panel): waist Circumference ≥40 (men) or ≥35 inches (women), Blood Pressure ≥135 (systole) or ≥85 (diastole) mmHg, Fasting Blood Sugar ≥100mg/dl, Triglycerides ≥150mg/dl, and High-Density Lipoproteins <40 (men) or <50 mg/dl (women). Of course the waist circumference size for Asian men is ≥90 cm and for Asian women is ≥58 cm. Not taking any drug that might affect blood pressure and glucose , insulin or lipid metabolism . Not having diabetes, liver or kidney diseases . Exclusion criteria: Patients will be excluded if they get gastrointestinal disorders or lose their interest to continue the study.

**Age**
From **25 years** old to **65 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **60**

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

**Randomization description**

**Blinding (investigator's opinion)**
Single blinded

**Blinding description**

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**
The 60 patients will randomly allocated to two group of metformin drug and low GI diet . As the patients register for entering the trial, they will be put in their own group according to their number.The method of randomization is drawing.

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Shiraz University of Medical Sciences.

**Street address**
Zand St. Shiraz

**City**
Shiraz

**Postal code**
14336 - 71348

**Approval date**
2013-08-04, 1392/05/13

**Ethics committee reference number**
CT-92-6678

## Health conditions studied

### 1

**Description of health condition studied**
metabolic syndrome

**ICD-10 code**
E00-E90

**ICD-10 code description**
Endocrine, nutritional and metabolic diseases

## Primary outcomes

### 1

**Description**
weight

**Timepoint**
before the intervention, 8weeks after the intervention

**Method of measurement**
seca weighing machine

### 2

**Description**
blood pressure

**Timepoint**
before intervention ,8weeks after intervention

**Method of measurement**
mmgh-piezometer

### 3

**Description**
lipid profile (TG,HDL,LDL,total Chol)

**Timepoint**
before intervention,8weeks after intervention

**Method of measurement**
biosystem autoanalyzer bt1500

### 4

**Description**
fasting blood sugar

**Timepoint**
before the intervention, 8 weeks after the intervention

**Method of measurement**
biosystem autoanalyzer bt1500

### 5

**Description**
waist circumference

**Timepoint**
before intervention ,8weeks after intervention

**Method of measurement**
centimeter-tape measure

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**
For the diet group the percentage of required energy will be calculated with Harris-Benedict formula.The percentage of macronutrients are the same for all participants and will be 50% carbohydrate,30%fat and 20% protein.The only difference to normal diet is the use of low-GI foods in the diet plan. The foods will be chosen from Foster-Powel Table , with medium (55-70) and low ( less than 55) glycemic index.
**Category**
Lifestyle

### 2

**Description**
The dose of administration for the metformin group will be 500mg (1 oral tab daily) for 8 weeks.
**Category**
Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Motahari Clinic
**Full name of responsible person**
Dr. Zohre Mazlom
**Street address**
Namazi Sq. Shiraz
**City**
Shieaz

## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Vice-Chancellery of Research and Technology, Shiraz University of Medical Sciences
**Full name of responsible person**
Dr. Mohammad Ali sahmoddini
**Street address**
Vice-Chancellery of Research and Technology,7th floor, Shiraz University of Medical Science Central Building, beside Helale-Ahmar, Zand Street, Shiraz
**City**
Shiraz
**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 and Technology, Shiraz 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**
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## Person responsible for scientific inquiries

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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*