

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Jul 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

Country

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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 ≥ 100 mg/dl, Triglycerides ≥ 150 mg/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

Shiraz

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 Sahmoudini

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

Name of organization / entity

Nutrition Faculty

Full name of responsible person

Dr. Zohre Mazlom

Position

Associate Professor of Nutrition

Other areas of specialty/work

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Person responsible for scientific inquiries

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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