

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jun 2026

The Effect of Pioglitazone on Left Ventricular Mass and Function, Plasma Levels of Inflammatory, Endothelial and Thrombotic Biomarkers and Psychiatric indicators in Non-Diabetic Patients with Metabolic Syndrome

Protocol summary

Summary

The objective of this study is to evaluate the effect of pioglitazone on left ventricular mass and function, plasma level of inflammatory, coagulative and endothelial biomarkers and psychiatric indicators in non-diabetic metabolic syndrome patients. This study is a randomized, double blind, placebo controlled trial. Males and females, aged 18 to 65 year-old with metabolic syndrome will be assigned into two groups of 70 persons each. Intervention group will receive pioglitazone 30 mg once daily and control group will receive matching placebo for 24 weeks. Plasma level of Quantitative C-reactive protein, Total Nitric oxide- Asymmetric Dimethylarginine, echocardiographic indices of left ventricular mass and function, stress level, severity of anxiety and depression and quality of life will be measured at the baseline and at the end of the trial. Patients will be followed up at weeks 6 and 18 by phone and at week 12 by interview and physical examination to evaluate medication tolerance and eventual side effects. Liver enzymes will be checked every 3 months, as well.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201101023733N2**

Registration date: **2011-02-14, 1389/11/25**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2011-02-14, 1389/11/25

Registrant information

Name

Masoumeh Sadeghi

Name of organization / entity

Isfahan Cardiovascular Research Center, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 31 1335 9696

Email address

roohafza@crc.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Isfahan Cardiovascular Research Center, Osvah Pharmaceutical Company, Army University Of Medical Sciences

Expected recruitment start date

2011-03-06, 1389/12/15

Expected recruitment end date

2011-05-05, 1390/02/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Pioglitazone on Left Ventricular Mass and Function, Plasma Levels of Inflammatory, Endothelial and Thrombotic Biomarkers and Psychiatric indicators in Non-Diabetic Patients with Metabolic Syndrome

Public title

The effect of Pioglitazone on Cardiovascular and Psychiatric status of non-Diabetic Metabolic Syndrome Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Male or Female 18 to 65 years of age, Patients with Metabolic Syndrome (National Cholesterol Education Program/ATP III Criteria), New York Heart Association Functional Class 1 or 2, BMI 25 to 32 kg/m²
Exclusion Criteria: Current or prior use of Pioglitazone or Rosiglitazone within the preceding 3 months, Current use of Glucocorticoids, Any history or evidence of ischemic heart disease, Patients with vulvular heart disease, Patients with uncontrolled hypertension (>140/90 mmHg), Patients with LV Systolic dysfunction diagnosed by Doppler Echocardiography (EF < 40%), Patients with Restrictive or Constrictive Cardiomyopathy and/or Pericarditis, Patients with Infectious Endocarditis, Patients with impaired Renal function (plasma creatinine > 1.5 mg/dl) or Hepatic function (ALT > 3 times of upper limit of normal), Chronic systemic inflammatory disease (eg. Rheumatoid disorders), Anemia (Hb < 13 mg/dl in Men & Hb < 12 mg/dl in Women), Pregnancy or Lactating, Alcohol or Drug abuse, Any debilitating medical condition

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **140**

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

Ethics committee of Isfahan Cardiovascular Research Center/Isfahan University of Medical Sciences

Street address

Seddigeh Tahereh Research and Treatment Hospital, Khorram Ave, Isfahan, IR. Iran

City

Isfahan

Postal code

Approval date

2010-10-18, 1389/07/26

Ethics committee reference number

89112

Health conditions studied

1

Description of health condition studied

Metabolic Syndrome

ICD-10 code

E88.9

ICD-10 code description

Metabolic disorder, unspecified

Primary outcomes

1

Description

Quantitative CRP

Timepoint

baseline- week 24

Method of measurement

Elisa kit

2

Description

early (E) and late (A) ventricular filling velocity

Timepoint

baseline- week 24

Method of measurement

Pulse wave Doppler Echocardiography

3

Description

Asymmetric Dimethylarginine

Timepoint

baseline- week 24

Method of measurement

Elisa kit

4

Description

Nitric Oxide

Timepoint

baseline- week 24

Method of measurement

Elisa kit

5

Description

-

Timepoint

-

Method of measurement

-

6

Description

Left Ventricular Mass

Timepoint

baseline- week 24

Method of measurement

2D and M-Mode Echocardiography

7

Description

Left Ventricular End Diastolic Diameter

Timepoint

baseline- week 24

Method of measurement

2D and M-Mode Echocardiography

8

Description

Severity of Anxiety and Depression

Timepoint

baseline- week 24

Method of measurement

Hospital Anxiety and Depression Scale (HADS) questionnaire

9

Description

Quality of Life

Timepoint

baseline- week 24

Method of measurement

EuroQol (EQ 5-D) questionnaire

10

Description

Myocardial early diastolic velocity (Em)

Timepoint

baseline- week 24

Method of measurement

Tissue Doppler Echocardiography

11

Description

stress level

Timepoint

baseline- week 24

Method of measurement

General Health Questionnaire (GHQ-12)

Secondary outcomes

1

Description

Plasma Lipoproteins

Timepoint

baseline - week 24

Method of measurement

Elisa kit

2

Description

Vital signs and General health status

Timepoint

baseline- weeks 6, 12, 18, 24

Method of measurement

Medical history and Physical Examination

3

Description

Body Mass Index and Waist circumference

Timepoint

baseline- weeks 12 and 24

Method of measurement

Scale- Tape measure

4

Description

Liver Transaminases

Timepoint

baseline- weeks 12 and 24

Method of measurement

Elisa kit

Intervention groups

1

Description

One Pioglitazone 30 mg Tablet per day for 24 weeks

Category

Treatment - Drugs

2

Description

One Placebo Tablet per day for 24 weeks

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Isfahan Cardiovascular Research Center (ICRC)

Full name of responsible person

Street address

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Osvah Pharmaceutical Company

Full name of responsible person

Dr. Saremi

Street address

17 Shahrivar St., Shad Abad - 7th Km. Karaj Old Road

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Osvah Pharmaceutical Company

Proportion provided by this source**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

2

Sponsor

Name of organization / entity

Army University of Medical Sciences

Full name of responsible person

Mrs. Ebrahimi

Street address

Etemad zade St.- West Fatemi Ave.

City

Tehran

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Army University of Medical Sciences

Proportion provided by this source**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**

Isfahan Cardiovascular Research Center

Full name of responsible person

Dr. Hamidreza Roohafza

Position

Assistant professor/Psychiatrist

Other areas of specialty/work**Street address**

Seddigheh Tahereh Research and Treatment Hospital,
Khorram Ave, Isfahan, IR. Iran

City

Isfahan

Postal code**Phone**

+98 31 1335 9898

Fax**Email**

roohafza@crc.mui.ac.ir

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Isfahan Cardiovascular Research Center

Full name of responsible person

Dr. Masoumeh Sadeghi

Position

Associated Professor/Cardiovascular Specialist

Other areas of specialty/work**Street address**

Seddigheh Tahereh Research and Treatment Hospital,
Khorram Ave, Isfahan, IR. Iran

City

Isfahan

Postal code**Phone**

+98 31 1335 9090

Fax**Email**

sadeghimasoumeh@gmail.com

Web page address

Person responsible for updating data

Contact

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