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- Asymmetic 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)

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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 hypertention (>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

Seddigheh 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
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Person responsible for scientific inquiries

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Name of organization / entity
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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