

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of Effects Metformin and pioGlutazon on Serum Osteoprotegerin and adiponectin in Patients with Type 2 diabetes in clinic of Imam Khomeini 2013

Protocol summary

Summary

The main goal: comparison of Effects Metformin and pioGlutazon on Serum Osteoprotegerin and adiponectin in patients with type 2 diabetes in Imam Khomeini clinic, Tehran, Iran in 2012-2013. Inclusion criteria: determination of Type 2 diabetes with ADA criteria ($FBS \geq 126$ or $HbA1C \geq 6.5$) and patients with newly diagnosed diabetes. Exclusion criteria: history of heart failure; Creatine > 1.5 mg/dl; liver failure; history of malignancy and being treated with insulin or other glucose-lowering drugs. Type of Study: RCT. Outcome: out Come of this two group are measured with The OPG and adiponectin levels and in each group after treatment had higher adiponectin are lower OPG may be a better indicator of the drug. Intervention method: patient are selected from Imam Khomeini clinic according to the inclusion and exclusion criteria from a group of patients treated with 500 mg twice daily are metformin and the other group was treated with 30 mg are pioGlutazon. At first, patients completed a questionnaire then referred to the endocrinology laboratory. samples were taken about 10 cc of blood at fasting (not eating food calories for 8 h), and samples will be maintained at $-70^{\circ}C$ until analysis. The reason of maintain blood in this study is that after 3 months, the patients were treated with two different drug's and their blood will be taken again and then both samples in the same conditions and at the same time with a kit of adiponectin Adiponectin Elisa kit AG-45A-0001EK-K101 and Osteoprotegerin in Human-opg kit BI-20402, and will be tested.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013041311356N2**
Registration date: **2014-04-12, 1393/01/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-04-12, 1393/01/23

Registrant information

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Alireza Esteghamati

Name of organization / entity

Tehran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Government and private

Expected recruitment start date

2013-04-18, 1392/01/29

Expected recruitment end date

2013-05-19, 1392/02/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Effects Metformin and pioGlutazon on Serum Osteoprotegerin and adiponectin in Patients with Type 2 diabetes in clinic of Imam Khomeini 2013

Public title

Effect of Metformin & Glutazon on cardiovascular disease

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: determination of Type 2 diabetes with ADA criteria (FBS $\geq$ 126 or HbA1C $\geq$ 6.5) and patients with newly diagnosed diabetes. Exclusion criteria: history of heart failure; Creatine > 1.5 mg/dl; liver failure; history of malignancy and being treated with insulin or other glucose-lowering drugs.

Age

From **30 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Tehran University of Medical Sciences

Street address

Corner Ghods, Keshavarz Blvd, Tehran

City

Tehran

Postal code**Approval date**

2012-12-21, 1391/10/01

Ethics committee reference number

91/130/2736/3

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

Diabetes

ICD-10 code

E10-14

ICD-10 code description

Diabetes mellitus

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

Adiponectin

Timepoint

first study- last study

Method of measurement

blood sampling

2**Description**

Osteoprotegerin

Timepoint

first study- last study

Method of measurement

blood sampling

Secondary outcomes**1****Description**

HbA1C

Timepoint

first study-last study

Method of measurement

Laboratory measurements of the HPLC method

2**Description**

FPG

Timepoint

first study-last study

Method of measurement

Elisa

3**Description**

HoMA-IR

Timepoint

first study-last study

Method of measurement

Fasting Insulin (μ u/ml) $\times$ FBS(mmol/l)/22/5

4**Description**

BMI

Timepoint

first study-last study

Method of measurement

Scales - Height Gauges

5

Description

Creatinine

Timepoint

first study-last study

Method of measurement

Elisa

6

Description

TG

Timepoint

first study-last study

Method of measurement

Elisa

7

Description

Chol

Timepoint

first study-last study

Method of measurement

Elisa

8

Description

LDL

Timepoint

first study-last study

Method of measurement

Elisa

9

Description

HDL

Timepoint

first study-last study

Method of measurement

Elisa

Intervention groups

1

Description

Intervention is giving pioglitazone to patients Dosage: 30 mg daily Duration of use: three month Frequency of consumption: a time pioglitazone hydrochloride structure: C19H20N2O3S•HCl

Category

Treatment - Drugs

2

Description

Control group are treated with metformin.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotohi

Street address

Qods corner, Keshavarz Blvd, Tehran

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

Imam Khomeini Hospital

Full name of responsible person

Dr. Raihane Azizi

Position

MD, Postgraduate Endocrinology

Other areas of specialty/work

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Bagher Khan, Imam Khomeini Hospital, Vali Asr Hospital

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Person responsible for scientific inquiries

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Name of organization / entity
Imam Khomeini Hospital
Full name of responsible person
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Other areas of specialty/work
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Person responsible for updating data

Contact

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Imam Khomeini Hospital

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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