Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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≥126 or HbA1C≥6.5) and patients with newly diagnosed diabetes. Exclusion criteria: history of hurt 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 ° 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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Name of organization / entity

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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≥126 or HbA1C≥6.5) and patients with newly diagnosed diabetes. Exclusion criteria: history of hurt 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/د

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
firs study- last study
Method of measurement
blood sampling

2

Description
Osteoprotegrin
Timepoint
firs 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 (µu/ml) ×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
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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