

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Comparing the effects of metformin versus Pioglitazone administration on 2 hours plasma ghrelin level in patients with type 2 diabetes referred to diabetes clinic of Imam Khomeini Medical Complex during 2011

Protocol summary

Summary

In this randomized clinical trial, we will recruit 60 patients with type 2 diabetic aged 30 years old or above. Patients will be chosen from new cases under treatment with diet and exercise or from patients that received only sulfonylurea and have not achieved good control by HbA1c >7% . After signing the informed consent, data including weight, height, waist and blood pressure will be measured for all patients. Patients will be randomly divided to 2 treatment groups: first group will receive metformin and pioglitazone for the second group. Baseline OGTT with 75 gr oral glucose will perform for all patients and blood samples will be collected after 0, 60 and 120 minutes. After treatment for three months, all of the patients will take the second OGTT. As a primary outcome, 2 hours plasma active gherlin after OGTT before and after 3 months treatment we compared between study groups In this study we examined 2 hours plasma active gherlin after OGTT before and after 3 months treatment with Metformin and pioglitazone.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102275917N1**

Registration date: **2011-05-04, 1390/02/14**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-05-04, 1390/02/14

Registrant information

Name

Hosein Moin Tavakkoli

Name of organization / entity

Endocrine Ward-Valiasr hospital-Tehran university of medical science (TUMS)

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Tehran university of medical science (TUMS)

Expected recruitment start date

2011-03-06, 1389/12/15

Expected recruitment end date

2011-06-22, 1390/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of metformin versus Pioglitazone administration on 2 hours plasma ghrelin level in patients with type 2 diabetes referred to diabetes clinic of Imam Khomeini Medical Complex during 2011

Public title

Evaluation of possible cause of weight change after Metformin and pioglitazone administration in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with known type 2 diabetes mellitus more than 30 years Serum creatinine < 1.5 mg/dl in men and <1.4 mg/dl in women Exclusion criteria: Serious cardiovascular diseases Advanced renal or hepatic diseases Severe diabetes mellitus complications Poor compliance

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 60

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 science (TUMS)

Street address

TUMS central building, ghods ave. , keshavarz boulevard

City

Tehran

Postal code**Approval date**

2011-03-05, 1389/12/14

Ethics committee reference number

130/1577/89/3

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

Diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Typell Diabetes mellitus

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

Plasma ghrelin

Timepoint

Before intervention, 3 month after intervention

Method of measurement

Serum ghrelin measurement after OGTT with 75 gram glucose

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

Leptin

Timepoint

Before intervention, 3month after intervention

Method of measurement

Plasma sample

2**Description**

BMI

Timepoint

Before intervention, 3month after intervention

Method of measurement

Weight/(height)²

3**Description**

Fasting plasma insulin

Timepoint

Before intervention, 3month after intervention

Method of measurement

Plasma sample

4**Description**

ALT

Timepoint

Before intervention, 3month after intervention

Method of measurement

Plasma sample

5**Description**

Triglyceride

Timepoint

Before intervention, 3month after intervention

Method of measurement

Plasma sample

6**Description**

LDL

Timepoint

Before intervention,3month after intervention

Method of measurement

Plasma sample

7**Description**

HDL

Timepoint

Before intervention,3month after intervention

Method of measurement

Plasma sample

8**Description**

Weight

Timepoint

Before intervention,3 month after intervention

Method of measurement

Weight scale

9**Description**

Fasting blood sugar

Timepoint

Before intervention,3month after intervention

Method of measurement

Plasma sample

10**Description**

Blood pressure

Timepoint

Before intervention,3 month after intervention

Method of measurement

Sphygmomanometer

11**Description**

HgbA1c

Timepoint

Before intervention,3month after intervention

Method of measurement

Plasma sample

Intervention groups**1****Description**

First group: Metformin 500 mg tablet orally bid for 3 month

Category

Treatment - Drugs

2**Description**

Second group: Pioglitazone 30 mg tablet orally daily for 3 month

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Diabetes Clinic, Imam khomeini medical complex

Full name of responsible person

Dr.Hosein moin tavakkoli

Street address

Imam khomeini medical complex , Bagherkhan ave.

City

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for Research, Tehran university of medical science (TUMS)

Full name of responsible person

Dr. Akbar Fotouhi

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TUMS Central Building, Ghods ave., Keshavarz boulevard

City

Tehran

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

Yes

Title of funding source

Vice chancellor for Research, Tehran university of medical science (TUMS)

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**

Endocrine ward,Valiasr hospital,TUMS

Full name of responsible person

Dr.Hosein Moin Tavakkoli

Position

Fellowship of Endocrinology

Other areas of specialty/work

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Person responsible for scientific inquiries

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Professor of Endocrine

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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