Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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/د

Health conditions studied

1

Description of health condition studied
Diabetes mellitus

ICD-10 code
E11

ICD-10 code description
TypeII 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
Tehran

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
Street address
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