

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of pioglitazone with sitagliptin effect on glycemic state in patients with uncontrolled diabetes 2 using metformin and sulfonylureas

Protocol summary

Summary

Objective: Comparison of pioglitazone with sitagliptin effect on glycemic state in patients with uncontrolled diabetes 2 using metformin and sulfonylureas Study design: Random block Study population: In this study, patients with uncontrolled type 2 diabetes treated with metformin and sulfonylureas presented to endocrine clinic of Shahid Rahimi hospital of Khorramabad from October 2016 to October 2017 will be considered. Inclusion criteria: patients with type 2 diabetes who are older than 18 years treated with 1500 mg metformin and 10-20mg sulfonylureas per day are included in the study. These patients should have HbA1c greater than 7, and fasting glucose greater than 126 mg / dL. Exclusion criteria 1. patients who have type 1 diabetes, 2. known case of heart disease and exertional dyspnea grade 3 and 4 3. kidney disease (GFR <30) 4. ALT / AST more than 3 times normal Sample size: 60 intervention or interventions studied: Group 1 : sitagliptin 50 mg plus metformin 1500 mg and sulfonylurea 10-20mg per day Group 2: pioglitazone 30 mg plus metformin 1500 mg and sulfonylurea 10-20mg per day intervention: 18.06.2016 to 19.06.2017 primary outcome: FPG, HbA1c, insulin, HOMA index, weight, HDL, TG, LDL, blood pressure

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016112631104N1**
Registration date: **2017-01-14, 1395/10/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-01-14, 1395/10/25

Registrant information

Name

Habib Moazami Goodarzi

Name of organization / entity

Lorestan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3333 6143

Email address

dr.goudarzi.h@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Lorestan University Of Medical Sciences

Expected recruitment start date

2016-06-18, 1395/03/29

Expected recruitment end date

2017-06-19, 1396/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of pioglitazone with sitagliptin effect on glycemic state in patients with uncontrolled diabetes 2 using metformin and sulfonylureas

Public title

Comparison of pioglitazone with sitagliptin effect in diabetes melitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patients with type 2 diabetes who are older than 18 years treated with 1500 mg metformin and 10-20mg sulfonylureas per day are included in the study.

These patients should have HbA1c greater than 7 and fasting glucose greater than 126 mg / dL. Exclusion criteria: 1) patients who have type 1 diabetes, 2) known case of heart disease and exertional dyspnea, grade 3 and 4 3) kidney disease (GFR <30), 4) ALT / AST more than 3 times normal

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**

Ethics committee of Lorestan University Of Medical Sciences

Street address

Kamalvand Pardis

City

Khorramabad

Postal code**Approval date**

2016-10-17, 1395/07/26

Ethics committee reference number

LUMS.REC.1395. 139

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

diabetes

ICD-10 code

E10-E14

ICD-10 code description**Primary outcomes****1****Description**

FPG, HbA1c

Timepoint

Before and three months after intervention

Method of measurement

mg/dl, %

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

Insulin, HOMA index, weight, HDL, TG, LDL, blood pressure

Timepoint

Before and three months after intervention

Method of measurement

Kg, mg/dl, mg/dl, mg/dl, mmHg

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

Intervention group 2: Using pioglitazone remedy. Abidi company pioglitazone 30 mg plus metformin 1500 mg and sulfonylurea 10-20mg per day for 12 weeks

Category

Treatment - Drugs

2**Description**

Intervention group 1: Using sitagliptin remedy. Abidi company sitagliptin 50 mg plus metformin 1500 mg and sulfonylurea 10-20mg per day for 12 weeks

Category

Treatment - Drugs

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

Endocrine clinic of Shahid Rahimi hospital of Khorramabad

Full name of responsible person

Foroozan Fathi

Street address

Shahid Rahimi hospital

City

Khorramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Lorestan University of Medical Sciences

Full name of responsible person

Dr Morovat Taheri Kalani

Street address

Kamalvand university campuses

City

Khorramabad

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 of Lorestan 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

Lorestan University of Medical Sciences

Full name of responsible person

Foroozan Fathi

Position

General Medicine

Other areas of specialty/work

Street address

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+98 66 3333 6143

Fax

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zm.sabzevari@yahoo.com

Web page address

Person responsible for scientific

inquiries

Contact

Name of organization / entity

Lorestan University of Medical Sciences

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Foroozan Fathi

Position

General Medicine

Other areas of specialty/work

Street address

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Name of organization / entity

Lorestan University of Medical Sciences

Full name of responsible person

Foroozan Fathi

Position

General Medicine

Other areas of specialty/work

Street address

Shahid Rahimi hospital

City

Postal code

Phone

00

Fax

Email

Web page address

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