Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)
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+98 66 3333 6143
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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

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Person responsible for scientific inquiries

Contact

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Foroozan Fathi

Position
General Medicine

Other areas of specialty/work

Street address
Shahid Rahimi hospital

City

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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