

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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**

Shahid Rahimi hospital

**City**

Khorramabad

**Postal code****Phone**

+98 66 3333 6143

**Fax****Email**

zm.sabzevari@yahoo.com

**Web page address**

### Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

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**Full name of responsible person**

Foroozan Fathi

**Position**

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### Person responsible for updating data

**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**

Shahid Rahimi hospital

**City****Postal code****Phone**

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**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*