

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Clinical Trial of Effect of Pioglitazone Therapy on hs-CRP and Lipid Profile in Diabetic Patients with Renal Transplantation

Protocol summary

Summary

This study designed to investigate the effects of pioglitazone on inflammatory processes in diabetic patients with kidney transplantation. Patients with diagnosis of diabetes, whom one month was passed after their transplantation, entered to the study. There were not any age or gender limitations. Cigarette smokers; patients with heart failure FC II and III; hepatitis B and C; GFR less than 30; pregnancy; acute rejection with progressive renal impairment and creatinine more than 1 mg/dl did not enter to the study. Patients divided randomly into two groups. First group received routine insulin therapy with daily one 15 mg pioglitazone tablet and second group received insulin therapy with placebo tablet for four months. Placebo tablets were produced identical in shape and size with pioglitazone by its manufacturer. Patients, researchers and data analyzer were unaware of drug compounds of two groups. At the beginning of the study height, weight and waist circumference measurements, heart, lung and lower extremity examinations carried out. Firstly, the patients' blood samples were taken to check for uric acid, lipid profile and hs-CRP. All patients were visited monthly, their blood glucose and creatinine were controlled by experiments and if any problems or side effects were seen, patients were excluded from study. After four months treatment, examinations and laboratory tests were performed again and compared between groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014050117413N2**

Registration date: **2014-05-12, 1393/02/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-05-12, 1393/02/22

Registrant information

Name

Hamidreza Karimi-Sari

Name of organization / entity

Student Research Committee, Baqiyatallah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2013-06-10, 1392/03/20

Expected recruitment end date

2013-12-22, 1392/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical Trial of Effect of Pioglitazone Therapy on hs-CRP and Lipid Profile in Diabetic Patients with Renal Transplantation

Public title

Therapeutic Effect of Pioglitazone in Diabetic Patients with Renal Transplantation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients who had undergone kidney transplantation at Labbafinejad hospital within one month after transplantation and diagnosis of diabetes had been confirmed, without age or gender limitation. Exclusion criteria: Cigarette smoker; patients with heart failure FC II & III; hepatitis B and C; GFR less than 30; pregnancy; acute rejection with progressive renal impairment; creatinine more than 1 mg/dl

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 58

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

Shahid Beheshti University of Medical Sciences, Daneshjoo Blvd, Daneshjoo Square, Evin, Tehran, IR.Iran.

City

Tehran

Postal code

Approval date

2013-06-02, 1392/03/12

Ethics committee reference number

135

Health conditions studied

1

Description of health condition studied

Insulin-dependent diabetes mellitus

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

2

Description of health condition studied

Non-insulin-dependent diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Non-insulin-dependent diabetes mellitus

3

Description of health condition studied

Kidney transplant failure and rejection

ICD-10 code

T86.1

ICD-10 code description

Kidney transplant failure and rejection

Primary outcomes

1

Description

Fasting blood glucose

Timepoint

Before treatment and after four months treatment

Method of measurement

Laboratory tests

2

Description

Blood uric acid

Timepoint

Before treatment and after four months treatment

Method of measurement

Laboratory tests

3

Description

Blood hs CRP

Timepoint

Before treatment and after four months treatment

Method of measurement

Laboratory tests

4

Description

Blood Triglyceride

Timepoint

Before treatment and after four months treatment

Method of measurement

Laboratory tests

5

Description

Blood Cholesterol

Timepoint

Before treatment and after four months treatment

Method of measurement

Laboratory tests

6

Description

Low density lipoprotein (LDL)

Timepoint

Before treatment and after four months treatment

Method of measurement

Laboratory tests

7

Description

High density lipoprotein (HDL)

Timepoint

Before treatment and six months after treatment

Method of measurement

Laboratory tests

Secondary outcomes

1

Description

Weight

Timepoint

Before treatment and after four months treatment

Method of measurement

Kilograms

2

Description

Body mass index

Timepoint

Before treatment and after four month treatment

Method of measurement

kg/m²

3

Description

Waist circle

Timepoint

Before treatment and after four months treatment

Method of measurement

Centimeter

Intervention groups

1

Description

Daily one 15 mg Pioglitazone tablet addition to routine insulin therapy for four months

Category

Treatment - Drugs

2

Description

Daily one placebo tablet addition to routine insulin therapy

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Labbafinejad Hospital

Full name of responsible person

Rana Arashnia

Street address

Shahid Labbafinejad Hospital, No#103, Boostan 9th St., Pasdaran Ave, Tehran, I.R. Iran.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Rana Arashnia

Street address

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City

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti 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

Students' Research Committee (SRC), Baqiyatallah
University of Medical Sciences, Tehran, IR Iran

Full name of responsible person

Hamidreza Karimi Sari

Position

General Practitioner

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Person responsible for scientific inquiries

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Full name of responsible person

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Postal code

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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