

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Effect of Pioglitazone on Blood glucose , inflammatory and oxidative stress markers after kidney transplantation in diabetic patients which are receiving Insulin

Protocol summary

Summary

This double-blind study comparing interventional prospective study is to determine the effect of pioglitazone on blood glucose, inflammatory markers and oxidative stress in diabetic patients receiving insulin after renal transplantation on 60 patients with diabetes recently kidney transplants have been done. The hospital's research center in Tehran will Labbafinejad martyr. The pioglitazone group will take the medication (30mg / d until glycemic control is achieved) and the second group will receive placebo for 4 months. Incoming patients to the study, including patients with diabetes, which is one month before the transplant, renal function should be stable and should be treated with insulin. Individuals with any history of having epidural early acute febrile and 30 ml / min GFR At baseline, hepatitis B, C, (New York Heart Association II-IV) CHF, pregnancy, received pulse corticosteroids, Acute rejection (disorder progressive renal an increase in creatinine mg / dl 1 and GFR drops below ml / min 30) 2 weeks before the study were excluded. The main objective of the study to achieve a fasting blood glucose 90-130 mg / dl and BS $\leq$ 160 mg / dl, and insulin dose will be calculated based on the. Intervals will visit patients every two weeks. Blood samples of 15 ml of venous blood to measure blood glucose levels, HbA1c, inflammatory markers: ESR, CRP, Faktvrhayaksydatyv stress: total protein carbonyls and malondialdehyde, IL-18 will be collected. The difference in the two groups during the medication is given.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012121811807N1**
Registration date: **2013-01-17, 1391/10/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-01-17, 1391/10/28

Registrant information

Name

Ali Kharazmkia

Name of organization / entity

Shahid Beheshti University of Medical Sciences,
Pharmacy faculty

Country

Iran (Islamic Republic of)

Phone

+98 21 2291 2501

Email address

a.kharazmkia@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2012-12-21, 1391/10/01

Expected recruitment end date

2013-08-22, 1392/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Pioglitazone on Blood glucose , inflammatory and oxidative stress markers after kidney transplantation

in diabetic patients which are receiving Insulin

Public title

Effect of Pioglitazone on kidney transplantation in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1-diabetis mellitus. 2- stable renal function at the initiation of study or 1 month after transplantation. 3- using insulin before study Exclusion criteria: 1- acute febrile episodes. 2- GFR less than 30 ml/dl before the study. 3-hepatitis B , C. 4- CHF (New York Heart Association II-IV) 5-pregnancy. 6-receiving pulse corticostroids. 7-Acute rejection at 2 week before of study starting.

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)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid beheshti pharmacy faculty

Street address

Niayesh junction - Valiasr Str.

City

tehran

Postal code

Approval date

2012-12-09, 1391/09/19

Ethics committee reference number

1391-1-94-9617

Health conditions studied

1

Description of health condition studied

Diabetis

ICD-10 code

E10

ICD-10 code description

Insulin-dependent diabetes mellitus

2

Description of health condition studied

Transplanted kidney

ICD-10 code

Z94.0

ICD-10 code description

transplanted kidney

Primary outcomes

1

Description

malondialdehyd plasma level

Timepoint

at the begining and end

Method of measurement

Pg/mL

2

Description

total protein carbonyls plasma level

Timepoint

at the begining and end

Method of measurement

Pg/mL kit

3

Description

IL-18 plasma level

Timepoint

at the begining and end

Method of measurement

(Pg/mL) kit

4

Description

Fast blood glucose

Timepoint

monthly

Method of measurement

kit (mg/dL)

5

Description

ESR level

Timepoint

monthly

Method of measurement

(Pg/mL) kit

6

Description

CRP plasma level

Timepoint

monthly

Method of measurement

(ng/mL) kit

7

Description

HbA1C level

Timepoint

monthly

Method of measurement

(mIU/mL) kit

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: 30 mg Pioglitazone once daily for 4 month

Category

Treatment - Drugs

2

Description

control group: placebo tablet once daily for 4 month

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Labafi nejad hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Deputy of Research and Technology, Shahid beheshti pharmacy faculty

Full name of responsible person

Dr. Afshin Zarghi

Street address

Valiasr street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Deputy of Research and Technology, Shahid beheshti pharmacy faculty

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Kharazmkia

Position

Resident of Pharmacotherapy

Other areas of specialty/work

Street address

Pharmacy faculty

City

Tehran

Postal code

Phone

+98 912 227 5713

Fax

Email

a.kharazmkia@sbmu.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Shadi Ziaee

Position

Asistant professor

Other areas of specialty/work

Street address

Valiasr street

City

Tehran

Postal code
Phone
+98 912 346 1497
Fax
Email
shadi_z73@yahoo.com
Web page address

Phone
+98 912 346 1497
Fax
Email
shadi_z73@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Shadi Ziaee
Position
Asistant of professor
Other areas of specialty/work
Street address
Pharmacy faculty
City
tehran
Postal code

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