Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effects of pioglitazone and linagliptin on glycemic control, lipid profile, and hs-CRP in patients with type 2 diabetes mellitus under treatment with metformin

Protocol summary

Study aim

Objective: The aim of this study is to compare the effects of pioglitazone and linagliptin on glycemic control, lipid profile, and hs-CRP in patients with type 2 diabetes mellitus under treatment with metformin.

Design

Study design: Randomized double-blind trial. Patients will be assigned into two groups to receive pioglitazone (n=30) or linagliptin (n=30).

Settings and conduct

Among patients with T2DM referred to Beheshti Clinic affiliated to Kashan University of Medical Sciences, 60 patients will be selected according to inclusion and exclusion criteria. Participants, investigators or the assessors of the outcomes are unaware of the study groups. Drugs are similar in shape and size. Fasting blood samples will be taken at baseline and 3 months after the intervention. Intervention period: 3 months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients diagnosed with type 2 diabetes, aged 30-50 years old. FBS ≥140. people under treatment with metformin for at least 3 months.
Exclusion criteria: Secondary diabetes due to cushing syndrome, acromegaly and other diseases, systemic inflammatory diseases such as rheumatoid arthritis, IBD, vasculitis, etc, renal or liver or heart failure, malignancy, under insulin therapy, pregnancy, unwillingness to cooperate.

Intervention groups

Intervention group1: 30 mg pioglitazone (Osveh pharmaceutical company, Tehran, Iran) daily, for 3 months orally. Intervention group2: 5 mg linagliptin (Alhavi pharmaceutical company, Tehran, Iran) daily, for 3 months orally.

Main outcome variables

Outcomes: fasting blood glucose (primary outcome) and lipid profile, serum hs-CRP, anthropometric indices, and HbA1c (secondary outcomes) will be quantified at study baseline and end-of-trial.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170513033941N66**
Registration date: **2019-10-28, 1398/08/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-28, 1398/08/06**
Update count: **0**

Registration date

2019-10-28, 1398/08/06

Registrant information

Name

Mohammadreza Sharif

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of pioglitazone and linagliptin on glycemic control, lipid profile, and hs-CRP in patients with type 2 diabetes mellitus under treatment with metformin

Public title

Comparison of pioglitazone and linagliptin

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients diagnosed with type 2 diabetes Individuals aged 30-50 years old FBS ≥140 under treatment with metformin for at least 3 months

Exclusion criteria:

Secondary diabetes due to cushing syndrome, acromegaly and other diseases systemic inflammatory diseases such as rheumatoid arthritis, IBD, vasculitis, etc. renal or liver or heart failure malignancy under insulin therapy pregnancy unwillingness to cooperate

Age

From **30 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly assigned into two groups. A randomization list will be generated from 1 to 60 by a random number generator (https://stattrek.com/statistics/random-number-generator.aspx) and patients were randomly assigned into each intervention group by their numbers. The block randomization technique (including AABB, BBAA, ABAB BABA, ABBA, BAAB) with 1:1 ratio will be used to achieve balanced group sizes. Drugs and placebos are in the same packaging at the Pharmaceutical company. Only the code is written on the packages. Patients and researchers do not know the type of drug and after analyzing the data, packet codes are decoded.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will be concealed from the researchers and participants until the final analyses are completed. Another person at the Beheshti clinic, who is not involved in the trial and not aware of random sequences, will be assigned the participants to the numbered bottles of drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kashan University of Medical Sciences

Street address

Ghotbe Ravandi Boulevard, Kashan

City

Kashan

Province

Isfehan

Postal code

8115187159

Approval date

2019-05-06, 1398/02/16

Ethics committee reference number

IR.KAUMS.MEDNT.REC.1398.016

Health conditions studied

1

Description of health condition studied

Type 2 diabetes mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

Fasting blood glucose levels

Timepoint

At the beginning of the study and after 3 months of intervention

Method of measurement

Enzymatic kit

Secondary outcomes

1

Description

HbA1c

Timepoint
At the beginning of the study and after 3 months of intervention
Method of measurement
HPLC

2

Description
Total cholesterol
Timepoint
At the beginning of the study and after 3 months of intervention
Method of measurement
Enzymatic kit

3

Description
High-density lipoprotein (HDL) cholesterol
Timepoint
At the beginning of the study and after 3 months of intervention
Method of measurement
Enzymatic kit

4

Description
Triglycerides
Timepoint
At the beginning of the study and after 3 months of intervention
Method of measurement
Enzymatic kit

5

Description
Low-density lipoprotein (LDL) cholesterol
Timepoint
At the beginning of the study and after 3 months of intervention
Method of measurement
Enzymatic kit

6

Description
high-sensitivity C-reactive protein (hs-CRP)
Timepoint
At the beginning of the study and after 3 months of intervention
Method of measurement
Elisa kit

7

Description
Weight
Timepoint
At the beginning of the study and after 3 months of intervention
Method of measurement
scale

8

Description
systolic and diastolic blood pressure
Timepoint
At the beginning of the study and after 3 months of intervention
Method of measurement
sphygmomanometer

Intervention groups

1

Description
Intervention group1: 30 mg pioglitazone (osveh pharmaceutical company, Tehran, Iran) daily, for 3 months orally.
Category
Treatment - Drugs

2

Description
Intervention group2: 5 mg linagliptin (Alhavi pharmaceutical company, Tehran, Iran) daily, for 3 months orally.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Beheshti Clinic
Full name of responsible person
Dr. Batol Zamani
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Ghotbe Ravandi Boulevard, Kashan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences

Full name of responsible person
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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
Kashan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Shadi yazdani
Position
Resident of Internal Medicine
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

Study Protocol
Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to

make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available