Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison Efficacy and Safety of Sitagliptin with Pioglitazon in patients with uncontrolled type 2 diabetes on metformin

Protocol summary

Summary

The aim of our study is to compare the therapeutic effect of pioglitasion and sitagliptin in blood sugar reduction in patients with uncontrolled type 2 diabetes undergoing Metformin treatment ; as a clinical study.According to the including criteria new cases of diabetes with the age of 30-60 years who have the HbA1C between 8-9.5% and BMI between 25 to 35 during the one past year entered our experiment. The predicted volume is 160 patients and are referred to the endocrinology clinic in Vali Asr hospital .The following items were checked in the beginning and at the 3rd month of treatment: HbA1C, TG, Chol, HDL, FBS,Bs 2hpp are analyzed in the laboratory and Blood Pressure, Body Weight will be recorded. . Our patients were randomly divided into two groups{random allocation}. The first group undergoing treatment with Metformin 1 to 2 gr daily and Pioglitasione 15 to 30mg daily, the other group undergoing treatment with Metformin 1 to2 gr daily and sitagliptin 100 to 50mg daily. All the patients were consulted by a nutritionist for the diabetic regimen. Patients were checked monthly to see if the treatment regimen were taken properly and in the case of exclusion criteria in the study will not be.(gastrointestinal and eye and kidney complications).in this study;reduction of HbA1C and FBS and Bs 2hpp as the primary outcome and improvement of lipid profiles and weight loss as a secondary outcome are discussed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015061619554N4**
Registration date: **2017-02-07, 1395/11/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-02-07, 1395/11/19

Registrant information

Name
Maryam Jameshorani
Name of organization / entity
Zanjan University of Medical Sciences
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Iran (Islamic Republic of)
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Email address
dr.shirinjameshorani@zumc.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research; Zanjan University of Medical Sciences

Expected recruitment start date

2016-04-19, 1395/01/31

Expected recruitment end date

2017-03-21, 1396/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison Efficacy and Safety of Sitagliptin with Pioglitazon in patients with uncontrolled type 2 diabetes on metformin

Public title

Sitagliptin and Pioglitazon effects in the treatment of diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Newly diagnosed type 2 diabetic patients In the past year ; HBA1C between 8 to 9.5; BMI between 35-25; Lack of insulin; written consent to participate in the study criteria ; Exclusion criteria: Liver problems (abnormal level of liver enzymes) (more than 1.5 times the normal); renal failure (BUN and CR abnormal) (creatinine increase greater than1.5); digestive problems (including dyspepsia, diarrhea, vomiting); acidosis (ie, ABG : PH <7/35) heart failure with EF below 35% ; macular edema eye

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **160**

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

1

Registry name

-

Secondary trial Id

-

Registration date

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Zanjan University of Medical Sciences

Street address

Zanjan university of medical sciences ;karmandan street;zanjan

City

Zanjan

Postal code

4415777978

Approval date

2015-11-21, 1394/08/30

Ethics committee reference number

ZUMS.REC.1394.215

Health conditions studied

1

Description of health condition studied

Diabetes mellitus type 2

ICD-10 code

(E10- E11-

ICD-10 code description

Insulin-dependent diabetes mellitus ,Non-insulin-dependent diabetes mellitus , Malnutrition-related diabetes mellitus Malnutrition-related diabetes mellitus , Unspecified diabetes mellitus

Primary outcomes

1

Description

HBA1C

Timepoint

Intervention and three months after intervention

Method of measurement

Elisa

2

Description

fasting blood glucose

Timepoint

Before and three months after intervention

Method of measurement

Elisa

3

Description

Bs2hpp

Timepoint

Before and three months after intervention

Method of measurement

Elisa

Secondary outcomes

1

Description

Weight

Timepoint

Intervention and three months after intervention

Method of measurement

Kg using scales

2

Description

TG

Timepoint
Before and three months after intervention
Method of measurement
Elisa

3

Description
CHOL
Timepoint
Before and three months after intervention
Method of measurement
Elisa

4

Description
HDL
Timepoint
Before and three months after intervention
Method of measurement
Elisa

Intervention groups

1

Description
tablet sitagliptin 50 to 100 mg and tablet metformin 1000 to 2000 mg daily (for3 month)
Category
Treatment - Drugs

2

Description
tablet pioglitazone 15 to 30 mg and tablet metformin 1000 to 2000 mg daily (for 3 month)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology clinic- Vali-Asr Hospital
Full name of responsible person
Maryam Jameshorani
Street address
Valiasr hospital; Valiasr Sq; Zanjan
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Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research; Zanjan University of Medical Sciences
Full name of responsible person
Alireza Shoghli
Street address
Zanjan university of medical sciences ;karmandan street;zanjan
City
Zanjan
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; Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
Maryam Jameshorani
Position
Specialist in Internal Medicine/Assistant Professor of University
Other areas of specialty/work
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Person responsible for updating data

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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