Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the Efficacy of Sitagliptin with Pioglitazone on the Control of Diabetic Patients

Protocol summary

Summary

The aim of this study, which is designed as a clinical test, is to investigate the effect of adding Sitagliptin and Pioglitazone in patients who their Glycemic status can't be controlled by Metformin and Sulfonylurea. Inclusion criteria:Diabetics Type II; taking complete doze of Metformin (1500-2000mg) and a Sulfonylurea (15-20mg); age range from 30 to 65; 7% ≤ HbAlc, Reluctance to take insulin; willingness to participate in the study and exclusion criteria: pregnant patient; patients with heart failure; patients with renal insufficiency; patients with bladder cancer background; Glycemic severe complications including DKA; Reluctance to participate in the study. Diabetics Type II who take complete doze of Metformin (1500-2000mg per day) and a Sulfonylurea (Glibenclamide 15-20mg per day) and their diabetes hasn't been controlled will be included in the study. Then they will be divided into two groups of equal numbers randomly. Pioglitazone 30mg will be prescribed for one group and Sitagliptin 100mg for the other group as a third medication. FBS (Fasting Blood Sugar) and HbA1c will be measured before the study and three months after the study. Variables such as age, sex, FBS and HbA1c will be studied. Hereby the effect of these two medications will be compared in term of their effectiveness and side effects.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201704246712N3**
Registration date: **2017-05-09, 1396/02/19**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-09, 1396/02/19

Registrant information

Name
Nasser Aghamohammadzadeh
Name of organization / entity
Tabriz University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research Tabriz University of Medical Science

Expected recruitment start date

2016-09-22, 1395/07/01

Expected recruitment end date

2017-09-23, 1396/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Efficacy of Sitagliptin with Pioglitazone on the Control of Diabetic Patients

Public title

Comparison of the Efficacy of Sitagliptin with Pioglitazone on the Control of Diabetic Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetics Type II; taking complete doze

of Metformin (1500-2000mg) and a Sulfonylurea (15-20mg); age range from 30 to 65; 7% ≤ HbAlc; Reluctance to take insulin; willingness to participate in the study. Exclusion criteria: pregnant patient; patients with heart failure; patients with renal insufficiency; patients with bladder cancer background; Glycemic severe complications including DKA; Reluctance to participate in the study.

Age
From **30 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **90**

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 Tabriz University of Medical Sciences

Street address
Central Bulding of Medical Science University, St. Golgasht, St. Azadi ,Tabriz

City
Tabriz

Postal code

Approval date
2010-09-23, 1389/07/01

Ethics committee reference number
IR.TBZMED.REC.1395.397

Health conditions studied

1

Description of health condition studied
Diabetes mellitus type 2

ICD-10 code
E10-E14

ICD-10 code description
Diabetes mellitus

Primary outcomes

1

Description
Fasting blood sugar

Timepoint
Before treatment and three months after starting the drug

Method of measurement
Test

2

Description
HbA1C

Timepoint
Before treatment and three months after starting the drug

Method of measurement
Test

Secondary outcomes

empty

Intervention groups

1

Description
In the first group Pioglitazone 30 mg daily as the third drug will be used.

Category
Treatment - Drugs

2

Description
In the second group Sytaglyptyn 100 mg daily medicine as the third drug will be used.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences, Imam Reza Hospital

Full name of responsible person
Dr. Nasser Aghamohammadzadeh

Street address
Department of Endocrinology, Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice Chancellor for Research of Tabriz University of Medical Sciences

Full name of responsible person
Dr. Mohammad Reza Rashidi

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Vice chancellor for Research of Tabriz University of Medical Sciences,Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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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
Vice Chancellor for Research of Tabriz 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
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Position
Endocrinology and Metabolism/ Associate Professor

Other areas of specialty/work

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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*