

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

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

#### Protocol summary

2017-05-09, 1396/02/19

#### 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% ≤ HbA1c, 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

#### Registrant information

##### Name

Nasser Aghamohammadzadeh

##### Name of organization / entity

Tabriz University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 41 1335 7850

##### Email address

aghamohammadzadeh@tbzmed.ac.ir

#### 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% ≤ HbA1c; 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. Goltasht, 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, Goltasht Street, Tabriz

**City**

## 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

**Street address**

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

**City**

Tabriz

**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**

Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Nasser Aghmohammadzadeh

**Position**

Endocrinology and Metabolism/ Associate Professor

**Other areas of specialty/work**

**Street address**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

### Contact

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Tabriz University of Medical Sciences

**Full name of responsible person**

Dr. Servin Dalil

**Position**

MD, Resident of Internal Medicine

**Other areas of specialty/work**

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Imam Reza Hospital, Tabriz University of Medical Sciences, Golgasht Street, Tabriz

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Sarvin.Dalil@Gmail.Com

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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*

