

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 May 2026

### The effect of Pioglitazone on the weight, lipid profile and liver enzymes in patients with type 2 diabetes

#### Protocol summary

##### Summary

Our aim in this study is to evaluate the effect of Pioglitazone on the weight, lipid profile and liver enzymes in patients with type 2 diabetes. The key inclusion criteria is to be between 35 and 75 years old on anti-diabetic drugs without any history of thiooglitanidione use and the main exclusion criteria is to have cirrhosis or advance congestive heart failure. In a randomized unicentral trial 220 type 2 diabetic patients from both genders referring to endocrinology clinic of Emam Reza hospital, Tabriz, Iran, will be assigned in two equal-sized groups control or intervention to receive 30 mg of pioglitazone daily for a 3-moths period. Patients in control group will not receive any drugs. Patients body weight, lipid profile, liver enzymes and fasting blood sugar level will be checked before and after the treatment to make comparisons between the groups.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201209276712N2**  
Registration date: **2012-12-31, 1391/10/11**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2012-12-31, 1391/10/11

##### 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

Tabriz University of Medical Sciences

##### Expected recruitment start date

2012-11-21, 1391/09/01

##### Expected recruitment end date

2013-02-19, 1391/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effect of Pioglitazone on the weight, lipid profile and liver enzymes in patients with type 2 diabetes

##### Public title

Glutazone effect on weight, lipid profile and liver enzymes in diabetics

##### Purpose

Health service research

##### Inclusion/Exclusion criteria

Inclusion criteria: Patients with the age between 35 and 75 years on anti-diabetic drugs; without any history of thiazolidindione use Exclusion criteria: patients who do not use anti diabetic drugs regularly or don't like to continue the study; patients with cirrhosis and advance congestive heart failure

##### Age

From **35 years** old to **75 years** old

##### Gender

Both

## Phase

N/A

## Groups that have been masked

No information

## Sample size

Target sample size: 220

## 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

Tabriz University of Medical Sciences

##### Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah Square

##### City

Tabriz

##### Postal code

51666-14756

#### Approval date

2012-07-02, 1391/04/12

#### Ethics committee reference number

9171

## Health conditions studied

### 1

#### Description of health condition studied

Type 2 diabetes mellitus

#### ICD-10 code

E11

#### ICD-10 code description

Non-insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

lipid profile

#### Timepoint

Before and after treatment

#### Method of measurement

laboratory testing

### 2

#### Description

liver enzyme

#### Timepoint

november 2012 to march 2013

#### Method of measurement

labratory

### 3

#### Description

weight

#### Timepoint

november 2012 to march 2013

#### Method of measurement

balance

## Secondary outcomes

### 1

#### Description

FBS

#### Timepoint

2012 novamner to march2013

#### Method of measurement

labratory

## Intervention groups

### 1

#### Description

randomized clinical trial with control group with oral 30 mg glutazone once a day for 3 month in intrvention group

#### Category

Treatment - Drugs

### 2

#### Description

For control group no drug will be administered.

#### Category

N/A

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Endocrinology clinic of Emam Reza hospital

##### Full name of responsible person

Naser Aghamohammadzadeh

##### Street address

Endocrinology clinic, Emam Reza hospital, Golgasht ave.

##### City

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Alireza Ostad Rahimi

**Street address**

Vice chancellor for research, Tabriz University of Medical Sciences, Daneshgah

**City**

Tabriz

**Grant name**

**Grant code / Reference number**

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

Yes

**Title of funding source**

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**

Naser Aghamohammadzadeh

**Position**

Associate professor/Endocrinologist

**Other areas of specialty/work**

**Street address**

Endocrinology ward, Emam Reza hospital, Golgasht ave.

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**Postal code**

**Phone**

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**Fax**

**Email**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Full name of responsible person**

Naser Aghamohammadzadeh

**Position**

Associate professor/Endocrinologist

**Other areas of specialty/work**

**Street address**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

Tabriz University of Medical Sciences

**Full name of responsible person**

Mehdi Hemmati

**Position**

General physician

**Other areas of specialty/work**

**Street address**

Endocrinology clinic, Emam Reza hospital, Golgasht ave.

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mehdi.hemmati@rocketmail.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*

**Data Dictionary**

*empty*