Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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 thioglitandione 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

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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 melitus
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 novamber 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
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Naser Aghamohammadzadeh
Position
Associate professor/Endocrinologist
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Person responsible for updating data

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Mehdi Hemmati
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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