

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of the effect Of Metformin and Pioglitazone on hypertriglyceridemia

Protocol summary

Study aim

Investigating and comparing the effect of Metformin and Pioglitazone in reducing triglycerides in patients with hypertriglyceridemia

Design

Clinical trial without control group, with two parallel groups, without blinding, simple randomized, single phase on 68 patients who are divided into two groups of 34 people.

Settings and conduct

Among the patients referred to the internal clinic of Khatam Al-Anbia Hospital, Shahrood, those who meet the criteria for inclusion in the study will be included in the study after obtaining consent and full explanations. They are randomly divided into two groups. The first group will receive metformin at a daily dose of 1000 mg and the second group will receive pioglitazone at a daily dose of 15 mg. At the beginning of the work, certain tests will be taken from the patients and at the end of 3 months, the tests will be repeated and compared.

Participants/Inclusion and exclusion criteria

Entry conditions : Age 25 to 70 years Triglycerides above 150 mg/dL BMI 25 to 40 Non-entry conditions: Not taking drugs affecting lipid profile No history of allergy to Metformin and Pioglitazone drugs and their categories Non-entry of diabetics due to previous use of drugs used in the study Non-entry of people with underlying disease

Intervention groups

The first group: including 34 people taking Metformin at a dose of 1000 mg per day, taking this drug after meals and with a full stomach to reduce the gastrointestinal side effects of the drug. The second group: including 34 people taking Pioglitazone at a dose of 15 mg per day, taking this medicine once a day.

Main outcome variables

Triglyceride; age, sex; weight; lipid profile; liver enzymes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230618058524N1**

Registration date: **2023-07-05, 1402/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2023-07-05, 1402/04/14**

Update count: **0**

Registration date

2023-07-05, 1402/04/14

Registrant information

Name

Amin Vesali

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5591 3473

Email address

amin-vesaly@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-07-01, 1402/04/10

Expected recruitment end date

2023-07-27, 1402/05/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect Of Metformin and Pioglitazone on hypertriglyceridemia

Public title
Comparison of the effect Of Metformin and Pioglitazone on hypertriglyceridemia(Dyslipidemia)

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age : 25 - 70 (male, female) Triglyceride over than 150 mg/dl 25 < BMI < 40 Not using of Metformin, Pioglitazone Not using of Statin drugs
Exclusion criteria:
Underlying diseases such as Diabetes, Hypothyroidism, Heart diseases, Kidney failure, Liver failure, Severe infections, Cancer, Inflammatory diseases such as Rheumatoid arthritis and Inflammatory bowel disease. Drug side effects caused by Metformin and Pioglitazone Patients with familial hypertriglyceridemia Patients with Osteoporosis Pregnancy Breastfeeding Having diabetes Alcohol consumption, Addictive drugs BMI > 40 kg/m2 Dissatisfaction with participating or continuing to attend the study Patients with special diets Users of Statins and other Fat-lowering drugs, Corticosteroids

Age
From **25 years** old to **70 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **68**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method will be used for randomization. The number of the sample size, that is 68, will be written on special plates from one to sixty eight. The plaques will be poured into a sphere and then will be stirred. A lottery will be drawn for each person and a number will be given to him. Even numbers will be in Metformin group and odd numbers will be in Pioglitazone group.

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 Islamic Azad University, Damghan branch
Street address
Saadi Square, Cheshme Ali Blvd
City
Damghan
Province
Semnan
Postal code
3671639998
Approval date
2023-04-04, 1402/01/15
Ethics committee reference number
IR.IAU.DAMGHAN.REC.1402.011

Health conditions studied

1
Description of health condition studied
Hypertriglyceridemia
ICD-10 code
E78.1
ICD-10 code description
Pure hyperglyceridemia

2
Description of health condition studied
Metabolic syndrom
ICD-10 code
E88.81
ICD-10 code description
Metabolic syndrome

Primary outcomes

1
Description
Triglyceride: It is one of the components of the lipid profile, which is one of the main diagnostic components and criteria in metabolic syndrome or insulin resistance syndrome, and has a direct relationship with the individual's insulin resistance conditions.
Timepoint
At the beginning of the intervention and then 3 months later
Method of measurement
Laboratory, Hitachi autoanalyzer with mg/dl scale

2
Description
Cholesterol: including total cholesterol, LDL, HDL, which are other components of the body's lipid profile. It has an active participation in the structure of the body and their quantity and quality is a predictive factor for cardiovascular events.

Timepoint

At the beginning of the intervention and then 3 months later

Method of measurement

Laboratory, Hitachi autoanalyzer with mg/dl scale

3

Description

Weight: Weight change is one of the results of treatment with some drugs. By measuring the weight in the study, results are also obtained regarding the effect of the drugs used on the weight of the patients.

Timepoint

At the beginning of the intervention and then 3 months later

Method of measurement

Digital scales in the clinic

4

Description

Liver function test: Including AST and ALT, which are liver function tests; Any increase in the level of these variables requires liver examination. These enzymes can increase in different cases. They also increase in fatty liver disorder in the field of metabolic syndrome. Their normal level is mostly up to 35.

Timepoint

At the beginning of the intervention and then 3 months later

Method of measurement

Laboratory, Hitachi autoanalyzer with U/L scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The group will be treated with metformin 1000 mg per day and will continue for three months, and at the end of the third month, re-evaluations will be done.

Category

Treatment - Drugs

2

Description

Intervention group: The group will be treated with pioglitazone 15 mg once a day and will continue for three months, and at the end of the third month, re-evaluations will be done.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam Al Anbia Hospital Shahrood

Full name of responsible person

Amin Vesali

Street address

Daneshgah Blvd ,Shahrud, Semnan Province, Iran

City

Shahrud

Province

Semnan

Postal code

3614871151

Phone

+98 23 3233 1876

Email

khatam@shahrood.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Nasrin Razavianzadeh

Street address

Khatam Hospital, Daneshgah Blvd, Shahrud, Semnan Province, Iran

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Phone

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Nasri_Razavianzadeh50@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nasrin Razavianzadeh

Position

Non-faculty specialist doctor

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

Street address

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Email

Nasrin_Razavianzadeh50@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Amin Vesali

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Amin Vesali

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available