Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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
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3614871151
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+98 23 3233 1876
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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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Email
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
Khatam al anbia Hospital, Daneshgah Blvd, Shahroud, Semnan province

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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

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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