Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Aug 2026

Comparison of the effect of pioglitazone and Gloranta on metabolic factors of patients with non-alcoholic fatty liver disease and type 2 diabetes

Protocol summary

Study aim
Comparison of the effects of pioglitazone and Glurenta on metabolic factors in patients with non-alcoholic fatty liver disease and type 2 diabetes referred to Clinic

Design
Single-blind, non-controlled phase 4 clinical trial on 72 patients

Settings and conduct
In this single-blind trial, the researchers involved in assessing the outcomes are unaware of the type of intervention that the patients receive. The study uses an independent person to collect the data, who has no connection to the intervention, and after the data is collected, the results are analyzed.Patients are assigned to groups using random blocks after obtaining informed consent. Also, in this study, no additional testing or costs are imposed on patients in addition to the diagnostic and treatment process.72 patients with diabetes and non-alcoholic fatty liver disease were divided into two groups of 36, one group receiving pioglitazone 15 mg daily and the other group receiving 10.5 mg daily. The dose of 10.5 mg of glorenta is an effective dose. After grouping, pioglitazone and glorenta are administered orally once a day for 6 months.

Participants/Inclusion and exclusion criteria
Patients aged 18 to 75 years with non-alcoholic fatty liver disease and type 2 diabetes No history of alcohol consumption (20 grams per day for women and 30 grams per day for men)

Intervention groups
72 patients with diabetes and non-alcoholic fatty liver disease were divided into two groups of 36, one group receiving pioglitazone 15 mg daily and the other group receiving 10.5 mg daily. The dose of 10.5 mg daily is an effective dose. After grouping, pioglitazone and 10.5 mg daily are administered orally for 6 months.

Main outcome variables
Lipid profile; BMI; Weight; Blood pressure; Liver enzymes; Fatty liver level; Blood sugar; Platelets; ESR, CRP

General information

Reason for update

Acronym
COEOPAG

IRCT registration information
IRCT registration number: **IRCT20250919067293N1**
Registration date: **2025-09-29, 1404/07/07**
Registration timing: **prospective**

Last update: **2025-09-29, 1404/07/07**
Update count: **0**

Registration date
2025-09-29, 1404/07/07

Registrant information

Name
Fatemeh Bahrampour

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 5517 3894

Email address
nemesisgrace@googlemail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-10-17, 1404/07/25

Expected recruitment end date
2026-04-20, 1405/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of pioglitazone and Gloranta on metabolic factors of patients with non-alcoholic fatty liver disease and type 2 diabetes

Public title

Comparison of the effect of pioglitazone and Gloranta on metabolic factors of patients with non-alcoholic fatty liver disease and type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18 to 75 years with non-alcoholic fatty liver disease and type 2 diabetes No history of alcohol consumption (20 grams per day for women and 30 grams per day for men) No history of cardiovascular events in the past 3 months Not pregnant or breastfeeding; active cancer or history of cancer treatment in the past 2 years; body mass index above 40 kg/m2.

Exclusion criteria:

Active or chronic hepatitis; cirrhosis and biliary disease; heart failure, renal dysfunction (eGFR <45 ml/min/1.73 m2) during the study Taking medications associated with fatty liver nonsteroidal anti-inflammatory drugs (NSAIDs) (amiodarone, tamoxifen, sodium valproate, corticosteroids, methotrexate). Simultaneous use of both drugs, Glurenta and Empagliflozin

Age

From **18 years** old to **75 years** old

Gender

Both

Phase

4

Groups that have been masked

- Data analyser

Sample size

Target sample size: **72**

More than 1 sample in each individual

Number of samples in each individual: **2**

Blood sample and ultrasound

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

In this single-blind trial, the researchers involved in assessing the outcomes are unaware of the type of intervention that the patients receive. The study uses an independent person to collect the data who has no connection to the intervention, and after the data is collected, the results will be analyzed.

Placebo

Not used

Assignment

Parallel

Other design features

no

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Baqiyatullah University of Medical Sciences

Street address

No. 24, Hakimian Alley, Badakhshan Kamali Street, Abuzar Street

City

Tehran

Province

Tehran

Postal code

1363935191

Approval date

2025-08-06, 1404/05/15

Ethics committee reference number

IR.BMSU.REC.1404.015

Health conditions studied

1

Description of health condition studied

Diabetes mellitus

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

2

Description of health condition studied

Non-alcoholic fatty liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Liver enzymes

Timepoint

Measurement of liver enzymes at the beginning of the study before the start of the intervention and 6 months after the start of Glurenta or pioglitazone

Method of measurement
A blood sample

2

Description
blood pressure
Timepoint
At the beginning of the study before the start of the intervention and 6 months after starting Glorenta or pioglitazone
Method of measurement
Blood pressure measuring device

3

Description
Body mass index of individuals
Timepoint
At the beginning of the study before the start of the intervention and 6 months after starting Glorenta or pioglitazone
Method of measurement
Scales and meters

4

Description
، LDL، HDL، Total cholesterol,Triglycerides
Timepoint
At the beginning of the study before the start of the intervention and 6 months after starting Glorenta or pioglitazone
Method of measurement
blood sample

5

Description
Fatty liver
Timepoint
At the beginning of the study before the start of the intervention and 6 months after starting Glorenta or pioglitazone
Method of measurement
The amount of liver fat is determined by ultrasound and fibroscan and based on the interpretation of the radiologist.

6

Description
(FBS، BS2hpp، Hba1c)
Timepoint
At the beginning of the study before the start of the intervention and 6 months after starting Glorenta or pioglitazone
Method of measurement
blood sample

7

Description
platelet
Timepoint
At the beginning of the study before the start of the intervention and 6 months after starting Glorenta or pioglitazone
Method of measurement
blood sample

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: 72 people with diabetes and non-alcoholic fatty liver disease were divided into two groups of 36 people: one group received pioglitazone 15 mg daily and the other group received 10.5 mg daily.The dose of Glurenta is 10.5 mg. An effective dose. Glurenta is administered orally once a day for 6 months. Then a blood sample is taken. Fasting blood glucose levels after 8 hours of fasting, blood levels of alanine aminotransferase (ALT), triglycerides (TG), free fatty acids (FFA) and CBC, ultrasound and cases requiring fibroscan are measured.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: 72 patients with diabetes and non-alcoholic fatty liver disease were divided into two groups of 36 people: one group received pioglitazone 15 mg daily and the other group received 10.5 mg daily. After grouping, pioglitazone was administered orally once a day for 6 months.Then a blood sample is taken. Fasting blood glucose levels after 8 hours of fasting, blood levels of alanine aminotransferase (ALT), triglycerides (TG), free fatty acids (FFA), and CBC, and ultrasound and in cases requiring fibroscan are measured.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Baqiyatullah Hospital Clinic
Full name of responsible person
Fatemeh Bahrampour
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Mohammad javad Behzad nia
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Bagheiat-allah University of Medical Sciences
Proportion provided by this source
1
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Fatemeh Bahrampour
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
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Latest degree
Medical doctor
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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
Yes - There is 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
Title and more details about the data/document
no
When the data will become available and for how long
6 months after results are published
To whom data/document is available
No body
Under which criteria data/document could be used
no
From where data/document is obtainable
no
What processes are involved for a request to access data/document
NO
Comments