

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of the effects of Metformin and gloreanta (Empagliflozin and linagliptin) on fatty liver of patients with type 2 diabetes in Ilam in 2021

Protocol summary

Study aim

Determining the effects of metformin and gloreanta (empagliflozin and linagliptin) on fatty liver in patients with type 2 diabetes

Design

Clinical trial with control group and intervention group, non-blind, simple randomized, phase 3 per 100 patients. For simple randomization of sealed envelopes containing blue and red cards that are randomly given to participants

Settings and conduct

Patients who refer to the hospital and the office of physicians specializing in gastroenterology and endocrinology and the objectives of the research are explained to them and if patients wish, they will enter the research.

Participants/Inclusion and exclusion criteria

1- Willingness to cooperate and complete the informed consent form by the patient 2- Patients over 18 years old 3- No pregnancy and breastfeeding 4- Do not consume alcohol

Intervention groups

The first group or the control group will receive standard treatment with metformin 500 mg tablets The second group receives Gloreanta tablets, which are a combination of 25 mg empagliflozin and 5 mg linagliptin. Patients will take the medication regimen for 12 weeks (3 months) and will be followed up

Main outcome variables

1- Further reduction in FBS and HBA1C 2- Further reduction in patients' weight and BMI 3- Further reduction in ALT enzyme levels

General information

Reason for update

Change sampling time Change the test time in the primary and secondary outcome variables Changing the number of pills in control and intervention groups Lack of

sufficient number of patients to collect Increase the duration of sampling

Acronym

IRCT registration information

IRCT registration number: **IRCT20210922052550N1**

Registration date: **2021-11-07, 1400/08/16**

Registration timing: **prospective**

Last update: **2022-07-23, 1401/05/01**

Update count: **3**

Registration date

2021-11-07, 1400/08/16

Registrant information

Name

Ali Karambeigi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 84 3222 4118

Email address

dr.karambeigi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-11, 1400/08/20

Expected recruitment end date

2022-09-22, 1401/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Metformin and gloreanta

(Empagliflozin and linagliptin) on fatty liver of patients with type 2 diabetes in Ilam in 2021

Public title

Comparison of the effects of metformin and gliclazide on fatty liver in patients with type 2 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Willingness to cooperate and complete the informed consent form by the patient Patients over 18 years of age No pregnancy and lactation Do not drink alcohol

Exclusion criteria:

Kidney disease Drugs sensitivity Diabetic ketoacidosis Exfoliative dermatitis and angioedema

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups by simple randomization with a sealed envelope. There are blue and red cards in the envelopes. Group 1 receives blue cards and the second group receives red cards randomly.

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 Ilam University of Medical Sciences

Street address

Ilam - Daneshjoo Blvd. - Mahdih St. - Maaref St. - Hekmat Alley

City

Ilam

Province

Ilam

Postal code

6931364447

Approval date

2021-10-04, 1400/07/12

Ethics committee reference number

IR.MEDILAM.REC.1400.119

Health conditions studied

1

Description of health condition studied

Fatty liver of type 2 diabetic patients

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

2

Description of health condition studied

Fatty liver of type 2 diabetic patients

ICD-10 code

E88.81

ICD-10 code description

Metabolic syndrome

3

Description of health condition studied

Fatty liver of type 2 diabetic patients

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

4

Description of health condition studied

Fatty liver of type 2 diabetic patients

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Determination and comparison of serum levels of alanine aminotransferase at the beginning and end of the study

Timepoint

Measurement of serum levels of alanine aminotransferase at the beginning of the study and three month later

Method of measurement

Serum levels of Alanine aminotransferase will be measured by a reagent laboratory and results will be obtained.

Secondary outcomes

1

Description

Determining and comparing the ratio of abdominal circumference to hip circumference at the beginning and end of the study

Timepoint

Measure the ratio of abdominal circumference to hip circumference at the beginning of the study and three month later

Method of measurement

Measure the ratio of abdominal circumference to hip circumference using an inelastic meter

2

Description

Determining and comparing ultrasound findings at the beginning and end of the study

Timepoint

Perform ultrasound at the beginning of the study and three months later

Method of measurement

Perform ultrasound by the selected ultrasound center and get the results

Intervention groups

1

Description

Control group: will receive metformin tablets, daily use (once) , drug dose: 500 mg, duration of use 12 weeks, number: 90 tablets, how to use: with breakfast, number of use: one daily, manufacturer : Amin Pharmaceutical Company

Category

Treatment - Drugs

2

Description

Intervention group: will receive gloreanta tablets, composition: empagliflozin 25 mg and linagliptin 5 mg, dose: 25/5mg, number of drugs: 90, how to use: with food, number of times: one daily tablet , Duration of use: 12 weeks, Manufacturer: Abidi Pharmaceutical Company

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid mostafa khomeini hospital Ilam

Full name of responsible person

Shahin Shabazi

Street address

1st Modarres, Razi Ave

City

Ilam

Province

Ilam

Postal code

6931934833

Phone

+98 84 3333 8228

Email

vcr@medilam.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ilam University of Medical Sciences

Full name of responsible person

Mohammad Reza Kaffashian

Street address

Ilam, Bangjanab, Research Blvd, Ilam University of Medical Sciences Campus, Vice Chancellor for Research and Technology

City

Ilam

Province

Ilam

Postal code

6939177143

Phone

+98 84 3223 5724

Email

vcr@medilam.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ilam University of Medical Sciences

Proportion provided by this source

100

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

Ilam University of Medical Sciences

Full name of responsible person

Shahin Shabazi

Position

Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Ilam, Shahid Keshvari Square, Shahed Hill, Shahid
Mostafa Khomeini Hospital
City
Ilam
Province
Ilam
Postal code
6931934833
Phone
+98 84 3333 8228
Email
Shahbazi-sh@medilam.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Shahin Shabazi
Position
Associate Professor
Latest degree
Subspecialist
Other areas of specialty/work
Internal Medicine
Street address
Ilam, Shahid Keshvari Square, Shahed Hill, Shahid
Mostafa Khomeini Hospital
City
Ilam
Province
Ilam
Postal code
6931934833
Phone
+98 84 3333 8228
Email
Shahbazi-sh@medilam.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Ilam University of Medical Sciences
Full name of responsible person
Ali Karambeigi
Position

Medical Student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Ilam, Daneshjoo Blvd., Mahdieh St., Maaref St.,
Hekmat Alley
City
Ilam
Province
Ilam
Postal code
6931364447
Phone
+98 84 3224 4119
Email
dr.karambeigi@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Information on the main outcome and outcome of the study

When the data will become available and for how long

Access period starts 6 months after the results are published

To whom data/document is available

People related to medicine and pharmacy

Under which criteria data/document could be used

In other subjects, using the results of this plan, the results can be used

From where data/document is obtainable

Ilam University of Medical Sciences data center and request by email to the project implementer

What processes are involved for a request to access data/document

After receiving the email from the applicant, the project manager will respond

Comments