Clinical Trial Protocol
Iranian Registry of Clinical Trials

04 Nov 2026

Comparison of the effects of Metformin and glorenta (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 glorenta (empagliflozin and linaglyptin) 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 Glorenta 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 glorenta

(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 glorenta 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. - Mahdieh 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 glorenta tablets, composition: ampagliflozin 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
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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

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Province

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6931934833

Phone

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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

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Ilam

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6931934833

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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

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6931364447

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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