

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Investigating the effect of empagliflozin on patients with non alcoholic fatty liver diseases

Protocol summary

Study aim

Clinical evaluation of empagliflozin with diabetic patient by non alcoholic fatty liver and investigating of sonography

Design

Clinical trial with control group , community_based and pragmatic , with parallel group , randomized, design of 30patient

Settings and conduct

Non random sampling : 30 diabetic patient with non alcoholic fatty liver in one groups of 30 people, is done in Farhikhtegan hospitals , investigating of sonography during the start of the test and then after 3 month treatment with empagliflozin investigating of sonography and comparison of them .

Participants/Inclusion and exclusion criteria

Inclusion criteria : Physician's diagnosis of diabetic patient with non alcoholic fatty liver , consent and cooperation of the patient to use the made capsule.
Exclusion criteria: change in regimen during the study , Male gender any history of gastric or dermatic hypersensitivity to products , use drugs for treatment non alcoholic fatty liver

Intervention groups

The case group of 30 diabetic patient with non alcoholic fatty liver are treatment with empagliflozin , and then investigating of the sonography after 3 month

Main outcome variables

Fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N18**

Registration date: **2023-09-02, 1402/06/11**

Registration timing: **retrospective**

Last update: **2023-09-02, 1402/06/11**

Update count: **0**

Registration date

2023-09-02, 1402/06/11

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

Country

Iran (Islamic Republic of)

Phone

+98 212640056

Email address

shiehmorteza@iaups.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-11, 1402/05/20

Expected recruitment end date

2023-09-02, 1402/06/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of empagliflozin on patients with non alcoholic fatty liver diseases

Public title

Empagliflozin in non alcoholic fatty liver

Purpose

Health service research

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic patient Fatty liver Empagliflozin

Exclusion criteria:

Drug use for fatty liver

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Other

Other design features

Investigating the effect of empagliflozin on diabetic patient with non alcoholic fatty liver

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Islamic Azad University

Street address

No.99, Yakhckal street, DR Shariati Avenue

City

TEHRAN

Province

Tehran

Postal code

193956466

Approval date

2023-04-18, 1402/01/29

Ethics committee reference number

IR.IAU.PS.REC.1402.041

Health conditions studied

1

Description of health condition studied

Diabetic patient with non alcoholic fatty liver

ICD-10 code

K75.8

ICD-10 code description

Other specified inflammatory liver diseases

Primary outcomes

1

Description

Different grades of fatty liver

Timepoint

Before the intervention and 30 days after it, the question paper and sonography and fibroscan analysis data will be evaluated.

Method of measurement

Investigating of sonography(fibroscan)

Secondary outcomes

1

Description

Investigating sonography related to the course of recovery during treatment

Timepoint

From the beginning of treatment for 3 month

Method of measurement

Examining the sonography of the patients

Intervention groups

1

Description

Intervention group : The case group are 30 patient with diabetic and non alcoholic fatty liver with treatment by empagliflozin in 3 month and then investigating of the result of empagliflozin by fatty liver by resulting of the sonography of patient

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Farhikhtegan Hospital

Full name of responsible person

Maryam Shiehmorteza

Street address

Islamic Azad Univesity Square, North Sattari, Tehran

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Province

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1477899679

Phone

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Email

Farhikhteganhospital@gmail.com

Web page address

<https://tms.iau.ir/farhikhtegan/fa/page/1272/>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Maryam Shiehmorteza

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No 99, Yasman Alley, Yakhchal street, Gholhak, Dr.
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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Mobina shieh

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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Person responsible for scientific inquiries

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Full name of responsible person

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Person responsible for updating data

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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

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

Title and more details about the data/document

The age, gender and demographic information of the patients as well as the results of the sonography and the

questionnaire containing the symptoms of the patients at the beginning, during and at the end of the treatment period by removing the individual characteristics of the patients can be shared.

When the data will become available and for how long

The release time of the documents and files is after the completion of the project and in the winter of 1402.

To whom data/document is available

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

By observing the ethical principles of concealment of information, documents and all the checks carried out on the information can be published.

From where data/document is obtainable

mobinashieh123@gmail.com

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

Sending request email

Comments