Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

The effect of Empagliflozine on the Non-Alcoholic Fatty Liver Disease in patients with type 2 diabetes mellitus

Protocol summary

Study aim

investigating the effect of empagliflozin on non-alcoholic fatty liver in type 2 diabetic patients referred to Loghman Hakim Hospital in 1400

Design

Sampling method: The non-probability sampling method will be targeted. In this way, random method is not used in selecting patients in each group, but from the available patients, patients in each group will be selected based on the researcher's judgment up to the specified volume (70 people in each group) according to the purpose of the study.

Settings and conduct

The present study, after obtaining permission from the ethics committee of Shahid Beheshti University of Medical Sciences and the consent of the head of the internal department of Loghman Hakim Hospital, will be conducted as a clinical trial on 140 type 2 diabetic patients referred to the endocrine / diabetes / gastrointestinal clinic in 1400. Patients are equally divided into control and treatment groups. In the treatment group, in addition to the standard treatment, they will receive 10 mg of Empagliflozin daily for 6 months. In the control group, patients received only standard treatment and did not receive Empagliflozin.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with type 2 diabetes in the age group of 20 to 70 years who are candidates for treatment with Empagliflozin. No history of Empagliflozin use -GFR> 35ml / min / 1.73mn2 -HbA1c≤7.5%

Intervention groups

Patients with type 2 diabetes and fatty liver treated with empagliflozin and placeo

Main outcome variables

Practical goals: 1.determining the level of insilin level,alt,ast,alkp,GGT,billi,FBS,HbA1c before and 3 and 6 months after the start of treatment 2.determining the degree of fatty liver by U.S and MRI before and 3 and 6 months after start if treatment 3.determining weigt and BMI before and 3 and 6 months after start of teratment

General information

Reason for update

Due to the spread of corona virus and lack of regular visits of patients to the clinic and the lack of a trend to treat diabetes with pioglitazone,the control group was tested with a placebo drug instead of pioglitazone,which did not contain empagliflozin and was prepared by a pharmaceutical company and available to type 2 diabetes patients with non alcoholics fatty liver who were under standard diabetes treatment.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210811052150N1**
Registration date: **2023-01-28, 1401/11/08**
Registration timing: **retrospective**

Last update: **2023-04-16, 1402/01/27**
Update count: **1**

Registration date

2023-01-28, 1401/11/08

Registrant information

Name
Fateme Shojaee
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 21 4407 4360
Email address
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-11, 1400/05/20

Expected recruitment end date

2022-05-10, 1401/02/20

Actual recruitment start date

2021-08-11, 1400/05/20

Actual recruitment end date

2022-03-11, 1400/12/20

Trial completion date

2022-09-11, 1401/06/20

Scientific title

The effect of Empagliflozine on the Non-Alcoholic Fatty Liver Disease in patients with type 2 diabetes mellitus

Public title

effect of Empagliflozine on the Non-Alchoholic Fatti Liver Disease

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes in the age group of 20 to 70 years who are candidates for treatment with Empagliflozine No history of using Empaglifozine GFR>35ml/min/1.7m2 HbA1c≤7.5% Satisfaction of patients or their legal guardians to attend the study and continue it

Exclusion criteria:

History of advanced liver and kidney disease Cardiac surgery or angioplasty planned within the last 3 months Bariatric surgery in last 2 years and other gastrointestinal surgeries that cause chronic malabsorotion Bleeding or any disorder in causing hemolysis or unstable red blood cells(such as malaria) Medical history of cancer(except basal cell cancer)or cancer treatment in the last 5 years treatment with anti-obesity drugs in the 3 months prior ti informed consent or any other treatment at the time of screening(i.e. surgery;aggressive dieting;etc)that results in an unstable body weight current treatment with systemic steroids or any uncontrolled endocrine disorder other than type 2 diabetes cinsumtion of alcohol or drugs in the last 3 months patients who during the treatment,another drug to control blood sugar was added to their teatment

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **140**

Actual sample size reached: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be simple and for each patient according to labeling initial amounts of the placebo (control group) and Empagliflozine(treatment group),using a randomizednumber chart.these same numbers will be written and sealed,and placed in a box for allocation concealment.The course of treatment for each patient will be selected by choosing the random numbers concealed in the box at the beginning of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study,blinding will e done for the patients as well aspart of the researchers who have the role of clinical caregivers and outcome assessors by coding packages containing empagliflozin and placebo which are apparently the same.Then these codes will be the number of patients in one envelope,will be cast and chosen randomaly.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Beheshti University of Medical Sciences

Street address

Makhsus avenu

City

Tehran

Province

Tehran

Postal code

1333625445

Approval date

2021-08-10, 1400/05/19

Ethics committee reference number

IR.SBMU.MSP.REC.1400.287

Health conditions studied

1

Description of health condition studied

Non-Alchoholic Fatty Liver Disease

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis (NASH)

Primary outcomes

1

Description
Degree of fatty liver in MRI
Timepoint
Before treatment and six months after treatment
Method of measurement
MRI

2

Description
body mass index
Timepoint
before and three and six monthns after treatment
Method of measurement
Kg/m2

3

Description
fasting blood sugar
Timepoint
before and three and six months after treatmen
Method of measurement
blood sampling

4

Description
HbA1C
Timepoint
before and three and six months after teatment
Method of measurement
blood sampling

5

Description
the level of liver transaminases
Timepoint
before and three and six months after treatmenet
Method of measurement
blood sampling

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients with Non-Alcoliholic Fatty Liver disease and type 2 Diabetes are under intervention with Empagliflozine at a dose of 10 and 25 mg based on FBS and HbA1c for 6 months and after 3 and 6 months in terms of FBS,HbA1c,AST,ALT,ALKP and degree of fatty liver they are examined in MRI and ultrasound.
Category
Treatment - Drugs

2

Description
Control group: Patients with Non-Alcoliholic Fatty Liver disease and type 2 Diabetes under standard diabetes treatment with placebo drug that did not contain empagliflozin based on FBS and HbA1c are monitored for 6 months in terms of FBS,HbA1c,AST,ALT,ALKP and liver grade fat is checked in MRI and ultrasound
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Loghman hakim hospital
Full name of responsible person
Fateme Shojaee
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Fateme Shojaee
Position
Researcher
Latest degree
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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