Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of the effect of Empagliflozin with Placebo on liver steatosis change in fibroscan in non diabetic patients with nonalcoholic fatty liver disease

Protocol summary

Study aim
The effect of Empagliflozin and placebo on fibroscan in nondiabetic patients with non-alcoholic fatty liver disease referred to Firoozgar hospital

Design
Randomized controlled clinical trial with parallel groups, triple blind

Settings and conduct
Nondiabetic patients with nonalcoholic fatty liver are referred to Firoozgar hospital will be randomized to two groups (A and B) and prescribed Empagliflozin in one group and placebo for another group with same coverage and researcher and patients and data analyzer will be blind to type of the drug. primary outcome is change in measured steatosis in fibroscan.

Participants/Inclusion and exclusion criteria
Inclusion criteria: 20 to 65 years, ALT more than 45 miligram/deciliter and more than 30 respectively in men and women, one of these items (fatty liver grade equals and more than 2 in liver sonography or controlled attenuation parameter (CAP) in fibroscan more than 230 decibels per meter. Exclusion criteria: alcohol consumption, autoimmune hepatitis, hepatitis B and C, Heart failure, renal failure, Consumption of Fibrate, statin, NSAIDs, Amiodarone, Tamoxifen, Zinc, Selenium and vitamin C and E, Empagliflozin, Metformin, Pioglitazone, corticosteroid, cirrhosis, cardiovascular disease, diabetes, pregnancy, breast feeding, cancer in 2 years ago, active hypothyroidism, body mass index more than 40 kilogram per square meter.

Intervention groups
Intervention Group: intake Empagliflozin 10 milligram once daily - Control Group: Placebo once daily

Main outcome variables
Primary endpoints: changes in CAP (marker of the liver steatosis in fibroscan) Secondary endpoints: changes in liver enzymes, lipid profiles, body composition (VAT area and A/G in DXA), LSM (marker of the liver fibrosis in fibroscan), NAFLD fibrosis risk score and FIB-4 index.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190122042450N1**
Registration date: **2019-05-13, 1398/02/23**
Registration timing: **prospective**

Last update: **2019-05-13, 1398/02/23**
Update count: **0**

Registration date
2019-05-13, 1398/02/23

Registrant information

Name
Mohammad Ebrahim Khamseh

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-05-21, 1398/02/31

Expected recruitment end date
2019-08-22, 1398/05/31

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Empagliflozin with Placebo on liver steatosis change in fibroscan in non diabetic patients with nonalcoholic fatty liver disease

Public title

The effect of Empagliflozin on nonalcoholic fatty liver disease in non-diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 20-65 Body mass index less than 40 Alcohol daily consumption <20 g in women and < 30 g in men, for at least 3 consecutive months over 5 years ago Hemoglobin A1c less than 6.5 percent Alanin aminotransferase more than 45 in men and more than 30 in women Creatinin less than 1.5 in men and less than 1.4 in women and glomerular filtration rate more than 45 Controlled atenuated parameter more than 230 in fibroscan or fatty liver grade equal and more than 2 in liver sonography Signature of consent form

Exclusion criteria:

Pregnancy, breast feeding Heart failure (class II to IV) History of cardiovascular disease in 3 months ago History of cancer in 2 years ago History of cirrhosis Abnormal TSH (uncontrolled yper or hypothyroidism) Autoimmune hepatitis (abnormal ANA and ASMA) Hepatitis C (positive HCV Ab) Hepatitis B (positive HBS Ag) Consumption of NSAIDs, Amiodarone, Tamoxifen, Fibrate, statin, Zinc, Selenium and vitamin C or other antioxidant drugs, Empagliflozin, Metformin, Pioglitazone, Vitamin E and other fatty liver drugs.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization method, 4 blocks

Blinding (investigator's opinion)

Triple blinded

Blinding description

Abidi's pharmacy place the empagliflozine and placebo in unique package and label as A, B and distribute between patients by non-notofied person while patient and investigator are not informed about type of drugs. Also, health-care and staffs of labroatory and radiology and fibroscan and DEXA are not informed about type of drugs. Also, outcome evaluator and data analyzer are not informed about type of drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2019-03-05, 1397/12/14

Ethics committee reference number

IR.IUMS.REC.1397.1119

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver disease

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis [NASH]

Primary outcomes

1

Description

change of CAP (Controlled attenuation parameter)

Timepoint

at start and 24 weeks

Method of measurement

with fibroscan

Secondary outcomes

1

Description
Weight
Timepoint
start and 12 weeks and 24 weeks after intervention
Method of measurement
with weight scale

2

Description
Nonalcoholic fatty liver disease fibrosis score
Timepoint
start and 24 weeks after intervention
Method of measurement
with use of labroatary tests and formula of the NAFLD fibrosis score

3

Description
FIB4 index
Timepoint
start and 24 weeks after intervention
Method of measurement
with use of labroatary tests and formula of the FIB4

4

Description
A/G (Android/Gynoid)
Timepoint
start and 24 weeks after intervention
Method of measurement
with Dual-energy X-ray absorptiometry (DEXA)

5

Description
Liver stiffness measurement (LSM)
Timepoint
start and 24 weeks after intervention
Method of measurement
Liver fibroscan

6

Description
VAT (Visceral adipose tissue)
Timepoint
start and 24 weeks after intervention
Method of measurement
with Dual-energy X-ray absorptiometry (DEXA)

7

Description
Body mass index
Timepoint
start and 12 weeks and 24 weeks after intervention
Method of measurement
with weight and height scale and formula

Intervention groups

1

Description
Intervention group: Empagliflozin 10 milligram, Dr. Abidi pharmacy over 6 months
Category
Treatment - Drugs

2

Description
Control group: placebo, Dr. Abidi pharmacy over 6 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Firoozgar hospital
Full name of responsible person
Seyedeh Hoda Taheri Otaghsara
Street address
Behafarin ST, Karimkhan AVE, Vali-asr Sq, Tehran, Iran
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hodataheri2463@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Dr. Kazem Malakuti
Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran
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research@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran University of Medical Sciences

Proportion provided by this source

75

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

2

Sponsor

Name of organization / entity

Abidi pharmacy

Full name of responsible person

Elham Andalib

Street address

Ahmed Qusayr Street (Bucharest), below the Argentine Square. Alley 13. No. 5

City

Tehran

Province

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1513815811

Phone

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Email

e.andalib@cobeldarou.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Abidi pharmacy

Proportion provided by this source

25

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyedeh Hoda Taheri

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Mohammad Ebrahim Khamseh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for updating data

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Name of organization / entity

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Seyedeh Hoda Taheri Otaghsara

Position

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Latest degree

Specialist

Other areas of specialty/work

Internal Medicine

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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