

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Aug 2026

Comparison of the effect of empagliflozin and pioglitazone and placebo on liver steatosis change in fibroscan in diabetic patients with non-alcoholic fatty liver disease

Protocol summary

Study aim

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

Design

Randomized controlled clinical trial with parallel groups, triple blind

Settings and conduct

Diabetic patients with nonalcoholic fatty liver are referred to Firoozgar hospital will be randomized to three groups (M, Z, Q) and prescribed Empagliflozin and Pioglitazone and placebo in each 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, diabetic with HbA1c 7-10, ALT more than 45 and 30 milligram/deciliter in men and women respectively, one of (fatty liver grade equals and more than 2 in sonography or controlled attenuation parameter 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 and corticosteroid, cirrhosis, cardiovascular disease, pregnancy, breast feeding, recently cancer, active hypothyroidism, body mass index more than 40 kilogram per square meter, diabetes type 1 or secondary diabetes.

Intervention groups

Intervention group 1: intake Empagliflozin 10 milligram once daily - Intervention group 2: pioglitazone 15 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 and HbA1c and FBS.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190122042450N3**

Registration date: **2019-05-24, 1398/03/03**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-24, 1398/03/03**

Update count: **0**

Registration date

2019-05-24, 1398/03/03

Registrant information

Name

Mohammad Ebrahim Khamseh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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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 and pioglitazone and placebo on liver steatosis change in fibroscan in diabetic patients with non-alcoholic fatty liver disease

Public title
The effect of empagliflozin on nonalcoholic fatty liver disease in diabetic patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age 20-65 Body mass index less than 40 Alcohol daily consumption less than 20 g in women and less than 30 g in men, for at least 3 consecutive months over 5 years ago Hemoglobin A1c 7-10 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 attenuated 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. Diabetes type 1 or secondary diabetes Consumption of corticosteroid for 14 days over 2 months ago biliary obstruction in liver and gallbladder sonography

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: **105**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method, 6 blocks

Blinding (investigator's opinion)
Triple blinded

Blinding description
Abidi's pharmacy place the empagliflozine and pioglitazone and placebo in unique package and label as Q, M, Z 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

2019-03-10, 1397/12/19

Ethics committee reference number

IR.IUMS.REC.1397.1221

Health conditions studied

1

Description of health condition studied

Nonalcoholic fatty liver disease

ICD-10 code

K75.81

ICD-10 code description

Nonalcoholic steatohepatitis [NASH]

2

Description of health condition studied

Diabetes type 2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

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 labroatory 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 labroatory 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

Intervention group: Pioglitazone 15 milligram, Dr. Abidi pharmacy over 6 months

Category

Treatment - Drugs

3

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

Haleh Chehrehgosha

Street address

Behafarin ST, Karimkhan AVE, Vali-asr Sq, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran 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

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

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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

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

Haleh Chehrehgosha

Position

Fellowship

Latest degree

Specialist

Other areas of specialty/work

Endocrinology & Metabolism

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Person responsible for scientific inquiries

Contact

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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

Contact

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Haleh Chehrehgosha
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Fellowship
Latest degree
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Other areas of specialty/work
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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