

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Aug 2026

A Comparison between the Effect of Empagliflozin and Pioglitazon on Echocardiographic Indices in Patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease

Protocol summary

Study aim

A Comparison between the Effect of Empagliflozin and Pioglitazon on Echocardiographic Indexes in Patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease

Design

Randomized, double-blind, Parallel-group, phase II clinical trial in 70 patients. Randomization was done through block randomization method.

Settings and conduct

Type 2 Diabetic patients with nonalcoholic fatty liver are referred to Firoozgar hospital will be randomized to two groups (A,B) and in the groups Empagliflozin and Pioglitazone will be prescribed with same coverage and researcher, patients and data analyzer will be blind to type of the drug.

Participants/Inclusion and exclusion criteria

Inclusion criteria : Type 2 diabetes mellitus (T2DM); HbA1C between 7-10.5%; NAFLD with cap score >300 dB/m ;Normal Ejection Fraction (EF≥50%). Non-inclusion criteria: Ischemic or non Ischemic heart disease ;Current use of SGLT2 inhibitors; Current use of Thiazolidendions ;Hepatitis B; Hepatitis C; Autoimmune Hepatitis; Alcohol consumption more than 30 gr/day in men; Alcohol consumption more than 20 gr/day in women; eGFR<45 cc/min/1.73 m2.

Intervention groups

Intervention group 1: 35 patients with type 2 diabetes and NAFLD will be treated with Empagliflozin 10 milligram, once daily for 24 weeks. Intervention group 2: 35 randomized patients with type 2 diabetes and NAFLD will be treated with Pioglitazone 30 milligram, once daily for 24 weeks.

Main outcome variables

Echocardiographic Indices

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190122042450N5**

Registration date: **2020-11-29, 1399/09/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-29, 1399/09/09**

Update count: **0**

Registration date

2020-11-29, 1399/09/09

Registrant information

Name

Mohammad Ebrahim Khamseh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8894 5246

Email address

khamseh.m@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-22, 1399/08/01

Expected recruitment end date

2021-03-21, 1400/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison between the Effect of Empagliflozin and Pioglitazone on Echocardiographic Indices in Patients with Type 2 Diabetes and Nonalcoholic Fatty Liver Disease

Public title

The cardiac effect of pioglitazone and empagliflozin among diabetic patients with NAFLD

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Type 2 diabetes mellitus (T2DM) HbA1C between 7-10.5% Non-alcoholic fatty liver disease (NAFLD) with cap score >302 dB/m Normal Ejection Fraction (EF≥50%)

Exclusion criteria:

Arrhythmia Ischemic or non Ischemic heart disease Peripheral artery disease Current use of SGLT2 inhibitors Current use of Glucagone like peptide 1 receptor agonist Current use of Thiazolidendions Current use of Tamoxifen Current use of Amiodarone Current use of Nonsteroid anti inflammatory agents Current use of Vitamin C Current use of Vitamin E Current use of Selenium Current use of other antioxidants Pregnancy Breast feeding Hypothyroidism Hyperthyroidism Cirrhosis Hepatitis B Hepatitis C Autoimmune Hepatitis Any form of chronic liver disease except fatty liver disease Alcohol consumption more than 30 gr/day in men Alcohol consumption more than 20 gr/day in women eGFR<45 cc/min/1.73 m2 Corticosteroid use at least 14 days in the past month Active cancer History of the treated cancer in the past 2 years. Current use of fibrates

Age

From **20 years** old

Gender

Both

Phase

2

Groups that have been masked

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

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The samples will be randomized by random blocking method with quadruple blocks and using a random number table of random allocation software .Blocking and allocation sequencing for concealment will be done by the non-research person.

Blinding (investigator's opinion)

Double blinded

Blinding description

Abidi's pharmaceutical company produces the empagliflozine and pioglitazone in the same package and labels them as A and B, distributes between patients by non-notified person while patient and investigator are

also not informed about type of the drugs. Also, health-care and staffs of laboratory and fibroscan and echocardiography are not informed about type of drugs. Also, outcome evaluator and data analyzer are not informed about type of drugs used by each group.

Placebo

Not 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

Shahid Hemmat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2020-03-18, 1398/12/28

Ethics committee reference number

IR.IUMS.REC.1398.1408

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**

Type 2 Diabetes

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes

3**Description of health condition studied**

Cardiomyopathy

ICD-10 code

I42

ICD-10 code description

Cardiomyopathy

Primary outcomes

1

Description

Echocardiographic Indices

Timepoint

At screening time (visit 1) and 24 weeks after the start of treatment (visit 7)

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Weight

Timepoint

At start ,after 12 weeks and 24 weeks

Method of measurement

weight scale

2

Description

Body mass index (BMI)

Timepoint

At start ,after 12 weeks and 24 weeks

Method of measurement

Calculation with formula

3

Description

Liver stiffness measurement (LSM)

Timepoint

At start and 24 weeks after intervention

Method of measurement

Liver fibroscan

4

Description

Nonalcoholic fatty liver disease fibrosis score

Timepoint

At start and 24 weeks after intervention

Method of measurement

By use of labroatary tests and formula of the NAFLD fibrosis score

5

Description

FIB4 index

Timepoint

At start and 24 weeks after intervention

Method of measurement

By use of laboratory tests and formula of the FIB4

6

Description

The change of CAP (Controlled attenuation parameter)

Timepoint

At start and 24 weeks

Method of measurement

By liver fibroscan

Intervention groups

1

Description

Intervention group 1: Empagliflozin 10 milligram, produced by Dr.Abidi pharmaceutical company, once daily for 6 months.

Category

Treatment - Drugs

2

Description

Intervention group 2: Pioglitazone 30 milligram, once daily, produced by Dr.Abidi pharmaceutical company, for 6 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

Fereshte Attaran

Street address

Behafarin street, Karimkhan street, Vali-asr square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyed Abbas Motavallian

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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
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
Iran University of Medical Sciences

Full name of responsible person
Fereshte Attaran

Position
Fellowship

Latest degree
Specialist

Other areas of specialty/work
Internal Medicine

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Institute of adult endocrinology and metabolism;
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Person responsible for scientific inquiries

Contact

Name of organization / entity
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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

Name of organization / entity
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Position
Fellowship

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Specialist

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

Yes - There is 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

Yes - There is 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

Title and more details about the data/document

Data will be published, if necessary, at the end of the study.

When the data will become available and for how long

One year after data collection.

To whom data/document is available

The researchers working at the university.

Under which criteria data/document could be used

The data will be used in research projects as the researchers required.

From where data/document is obtainable

Corresponding author

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

After receiving the proposal data will be available for the researchers.

Comments