Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Nov 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 Pioglitazon 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
Echocardiograghy

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
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8214 1600
Email
Fereshte1Attaran@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Seyed Abbas Motavallian
Street address
Hemmat highway

City
Tehran
Province
Tehran
Postal code
۱۴۴۹۶۱۴۵۳۵
Phone
+98 21 8670 2030
Fax
+98 21 8862 2692
Email
ivco@iums.ac.ir
Web page address
https://iums.ac.ir/fa?sid=120

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
Street address
Institute of adult endocrinology and metabolism; Firooze alley; Karimkhan avenue; Vali-asr square
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8894 5246
Email
Fereshte1Attaran@gmail.com

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
Street address
Institute of adult endocrinology and metabolism; Firooze alley; Karimkhan avenue; Vali-asr square
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8894 5246
Fax
+98 21 8894 5173
Email
khamseh.m@iums.ac.ir
Web page address
https://iem.iums.ac.ir/page/8501/home-page

Person responsible for updating data

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
Street address
Institute of adult endocrinology and metabolism; Firooze alley; Karimkhan avenue; Vali-asr square
City
Tehran
Province
Tehran
Postal code
1593747811
Phone
+98 21 8894 5246
Email
Fereshte1Attaran@gmail.com

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