

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of empagliflozin on serum erythropoietin level ,hematopoietic indices indices and the positive short term echocardiographic changes in type 2 diabetic patients with coronary artery disease

Protocol summary

Study aim

The main objective of this study was to evaluate the changes in serum erythropoietin levels following the use of empagliflozin and the relationship between these changes and the possible improvement of cardiac and renal function in type 2 diabetic patients.

Design

Patients were divided into two groups of 45 intervention and control groups by random number table and after adjusting for demographic characteristics and followed for 6 months.

Settings and conduct

Patients with type 2 diabetes and proven coronary heart disease with previous angiography who do not have appropriate control for diabetes. All tests and echocardiography were performed in Ayatollah Mousavi hospital in Zanjan. Patients were matched in two intervention and control groups. The face is double-sided (patient and confused)

Participants/Inclusion and exclusion criteria

Type 2 diabetic patients Age over 40 years
Cardiovascular disease proven by coronary angiography
A1c between 7 and 9

Intervention groups

In the intervention and control groups, blood levels of erythropoietin, hematocrit, urinary albumin / creatinine ratio, and echocardiography and ECG were measured before and after 6 months of empagliflozin and placebo.

Main outcome variables

Serum Erythropoietin Level - Serum Hematocrit Level -
Urinary Albumin to Creatinine Ratio

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190806044451N1**

Registration date: **2019-10-07, 1398/07/15**

Registration timing: **registered_while_recruiting**

Last update: **2019-10-07, 1398/07/15**

Update count: **0**

Registration date

2019-10-07, 1398/07/15

Registrant information

Name

Farzane Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

metabolic1397@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-29, 1398/06/07

Expected recruitment end date

2020-03-19, 1398/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of empagliflozin on serum erythropoietin level ,hematopoietic indices indices and the positive short term echocardiographic changes in type 2 diabetic

patients with coronary artery disease

Public title
The effect of empagliflozin on improvement of hematopoiesis in diabetic cardiovascular patient

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
type2 diabetes age more than 40 established cardiovascular disease with angiography HbA1c between 7 to 9
Exclusion criteria:
heart failure (EF<40 %) history of myocardial infarction or un stable angina during 6 month ago Recent anemia severe kidney disease(GFR<30)

Age
From **40 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
The randomization method in this study is simple randomization and the randomization unit is also individual. People in this study will be divided into two groups without specific bias.

Blinding (investigator's opinion)
Double blinded

Blinding description
Patients are divided into two groups of intervention and control by the person who has no role in the process of execution and analysis of the data, and the drug and placebo are given after initial prototyping and cardiac echocardiography.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Zanjan University of Medical Sciences

Street address
Metabolic deases researchs center hospital shariati
Blv Zanjan

City
Zanjan

Province
Zanjan

Postal code
4515613191

Approval date
2019-06-02, 1398/03/12

Ethics committee reference number
IR.ZUMS.REC.1398.062

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus type 2

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

2

Description of health condition studied

Coronary artery disease

ICD-10 code

I125.1

ICD-10 code description

Atherosclerotic heart disease of native coronary artery

Primary outcomes

1

Description

duration of illness

Timepoint

six month

Method of measurement

questionnaire

2

Description

drug history

Timepoint

six month

Method of measurement

questionnaire

3

Description

empagliflozine

Timepoint

period six month

Method of measurement

questionnaire

4

Description

erythropoietin level

Timepoint

six month

Method of measurement

ELAISA

5

Description

spot albumin to Cr

Timepoint

six month

Method of measurement

dip stick

6

Description

Serum hemoglobin levels before and after treatment

Timepoint

six month

Method of measurement

immunochemilossent

7

Description

echocardiography

Timepoint

six month

Method of measurement

echocardiography device

Secondary outcomes

1

Description

1. Evaluation of changes in serum erythropoietin levels before and after the use of empagliflozin compared with placebo in diabetic patients with stable cardiovascular disease2. Evaluation of the relationship between changes in serum erythropoietin level and changes in hematopoietic indexes before and after the use of empagliflozin compared with placebo in diabetic patients with stable cardiovascular disease3. Evaluation of the relationship between changes in serum erythropoietin level and Alb / cr changes before and after the use of empagliflozin compared with placebo in diabetic patients with stable cardiovascular disease4. Evaluation of the relationship between changes in serum erythropoietin level and the magnitude of changes in echocardiographic indices before and after the use of empagliflozin compared with placebo in diabetic patients with stable cardiovascular disease5. Evaluation of the relationship between changes in FBS, HbA1c and serum levels of erythropoietin before and after the use of empagliflozin compared with placebo in diabetic patients with stable cardiovascular disease6. Evaluation of fasting serum insulin level in patients taking oral hypoglycemic

drugs before and after empagliflozin compared with placebo in diabetic patients with stable cardiovascular disease7. Evaluation of the relationship between changes in echocardiographic indices with Alb / cr before and after the use of empagliflozin compared with placebo in diabetic patients with stable cardiovascular disease

Timepoint

At a six-month interval after the administration of empagliflozin and placebo

Method of measurement

ELISA KIT

Intervention groups

1

Description

Intervention group: Diabetic patients with proven cardiovascular disease will be treated with a 10 mg dose of empagliflozin at a six-month interval in addition to their previous treatment.

Category

Treatment - Drugs

2

Description

Control group: Patients in the control group are diabetic patients with proven cardiovascular disease who receive placebo over a six-month period in addition to their previous treatments.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Reyhaneh Mahmoodian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Dr. Hassan Ahangar

Street address

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Dr. Abidi Pharmaceutical Company

Proportion provided by this source

50

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**

Persons

Person responsible for general inquiries

Contact**Name of organization / entity**

Zanjan University of Medical Sciences

Full name of responsible person

Dr Reyhaneh Mahmoodian

Position

Endocrine Fellowship

Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available	information retained for publication.
Study Protocol	When the data will become available and for how long
Yes - There is a plan to make this available	From 2020- on wards the basis of the letter of the publisher magazine
Statistical Analysis Plan	To whom data/document is available
Yes - There is a plan to make this available	All members of the medical community
Informed Consent Form	Under which criteria data/document could be used
Yes - There is a plan to make this available	In coordination with the responsible person and in writing and with the consent of the patients
Clinical Study Report	From where data/document is obtainable
Yes - There is a plan to make this available	To the email or mobile phone number of the responsible person
Analytic Code	What processes are involved for a request to access data/document
Undecided - It is not yet known if there will be a plan to make this available	After publishing an article in a prestigious journal, it is decided on the basis of the journal's letter
Data Dictionary	Comments
Undecided - It is not yet known if there will be a plan to make this available	
Title and more details about the data/document	
After analyzing the data and defending the thesis, an article is sent to a reputable journal with the patient	