Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 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 ampoglifluosine 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)
Phone
+98 24 3377 0758
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 hematopeosis in diabetic cardiovascular patient
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
type2 diabetes age more than 40 stablished 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
erythropoetin 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
immunoichemilosent

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 impagliflozin 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 ampogliflozin 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 ampoglifluosine 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 ampogliflozin 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 ampogliflosin 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 impagliflozin 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 ampoglifluosine compared with placebo in diabetic patients with stable cardiovascular disease
Timepoint
At a six-month interval after the administration of empagliflosine 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 ampogliflozin 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
Street address
Metabolic diseases researchs center valiasr Hspital Shariati Blv
City
Zanjan
Province
Zanjan
Postal code
4515777978
Phone
+98 24 3377 0758
Email
reyhanehmahmoodian@Gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Hassan Ahangar
Street address
Zanjan University of Medical Sciences Central Azadi Blvd.
City
Zanjan
Province
Zanjan
Postal code
45156-13133
Phone
+98 24 3342 4767
Fax
+98 24 3342 4769
Email
Education@zums.ac.ir
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
Endocine Fllowship
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Shariati Blvd
City
Zanjan
Province
Zanjan
Postal code
4515777978
Phone
+98 24 3377 0758
Fax
Email
Metabolic1397@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr Reyhaneh Mahmoodian
Position
Endocrine Fllowship
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Zanjan - Metabolic Center of Valiasr Hospital
City
Zanjan
Province
Zanjan
Postal code
4515777978
Phone
+98 24 3377 0758
Email
reyhanehmahmoodian@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Dr. Reyhaneh Mahmoodian
Position
Endocrine Fllowship
Latest degree
Specialist
Other areas of specialty/work
Internal Medicine
Street address
Shariati Boulevard Metabolic Center of Valiasr Hospital
City
Zanjan
Province
Zanjan
Postal code
4515777978
Phone
+98 24 3377 0758
Email
reyhanehmahmoodian@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is 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

After analyzing the data and defending the thesis, an article is sent to a reputable journal with the patient information retained for publication.

When the data will become available and for how long

From 2020- on wards the basis of the letter of the publisher magazine

To whom data/document is available

All members of the medical community

Under which criteria data/document could be used

In coordination with the responsible person and in writing and with the consent of the patients

From where data/document is obtainable

To the email or mobile phone number of the responsible person

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

After publishing an article in a prestigious journal, it is decided on the basis of the journal's letter

Comments