

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

To Study the effect of Empagliflozin on the cardiovascular biomarkers Galectin-3 and sST-2 in type 2 diabetic patients myocardial infarction with requiring primary angioplasty

Protocol summary

Study aim

Investigating the effect of Empagliflozin on Galectin-3 and sST-2 gene expression in type 2 diabetic patients with heart infarction and requiring primary angioplasty

Design

The study will be conducted as a clinical trial with a control group, randomized double-blind, phase 4 on 60 patients. Randomization will be done by random allocation rule method and sequence of even and odd codes.

Settings and conduct

Selection of patients from type 2 diabetic patients with ST elevation myocardial infarction admitted to Ayatollah Mousavi Hospital in Zanjan Taking the initial blood sample one day before the discharge of each patient, randomly prescribing empagliflozin or placebo and the follow-up blood sample at the end of 3 months Extracting total RNA from samples and performing Real Time PCR to check the expression of genes Entering data into SPSS software and using paired t test and Willcoxon test Patient, researcher and healthcare personnel are blind and aren't aware of the codes and groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetic patients with ST elevation myocardial infarction (STEMI) Non-entry criteria: Cardiogenic shock; hypoglycemia; diabetic ketoacidosis; history of coronary artery bypass surgery; type 1 diabetes, severe liver failure; history of severe sensitivity to empagliflozin or its formulation components; severe renal failure, end-stage renal disease(ESRD) or dialysis; hypovolemia; any inflammatory disease under treatment; end stage cancer and history of any cancer; advanced heart failure

Intervention groups

Intervention: type 2 diabetic patients treated with oral drugs, receiving empagliflozin from ABIDI Pharmaceutical Company in the form of 10 mg tablets, once a day orally

for 3 months Control: type 2 diabetic patients treated with oral drugs, receiving placebo for 3 months

Main outcome variables

Cardiac biomarkers Galectin-3 and sST-2

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230724058910N1**

Registration date: **2023-08-07, 1402/05/16**

Registration timing: **prospective**

Last update: **2023-08-07, 1402/05/16**

Update count: **0**

Registration date

2023-08-07, 1402/05/16

Registrant information

Name

Mahnaz Yousefi ramandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 912 883 3831

Email address

mahnaz.yousefi70@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-08-23, 1402/06/01

Expected recruitment end date

2024-01-20, 1402/10/30

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
To Study the effect of Empagliflozin on the cardiovascular biomarkers Galectin-3 and sST-2 in type 2 diabetic patients myocardial infarction with requiring primary angioplasty

Public title
To Study the effect of Empagliflozin on the cardiovascular biomarkers in diabetic patients myocardial infarction

Purpose
Basic science

Inclusion/Exclusion criteria
Inclusion criteria:
 Type 2 diabetic patients (Hb A1C: 6.5-8) Diabetes treated with oral agents Typical chest pain during the 12 hours before presentation lasting more than 30 minutes ST-segment elevation above 0.1 mV in two leads or more in ECG
Exclusion criteria:
 Cardiogenic shock Diabetic ketoacidosis History of CABG Type 1 diabetic patients Severe liver failure End stages cancer or history of any cancer History of severe allergy to empagliflozin or its formulation components Severe renal failure (eGFR <30 mL/minute/1.73 m²), end-stage renal disease (ESRD), or dialysis Hypovolemia Any inflammatory disease under treatment Advanced heart failure Hypoglycemia

Age
No age limit

Gender
Both

Phase
4

Groups that have been masked

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

Sample size
Target sample size: 60

Randomization (investigator's opinion)
Randomized

Randomization description
By coding the third person (collaborator), drug and placebo are divided into odd and even groups. With the random allocation rule method, a set of 30 even codes and 30 odd codes are placed in a lottery container, and the codes are randomly removed from the container without replacement, and the created sequence is recorded, and the medicine is given to the patients based on that.

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be conducted as a double-blind clinical trial. In this study, the researcher, the patient and the healthcare personnel do not know whether the patient is being treated with medicine or placebo. By coding the third person (collaborator), the drug and placebo are divided into two groups and given to the patients randomly.

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
 Professor Youssef Sobouti Blvd., Zanjan University of Medical Sciences
City
 Zanjan
Province
 Zanjan
Postal code
 4513956184
Approval date
 2023-07-04, 1402/04/13
Ethics committee reference number
 IR.ZUMS.REC.1402.099

Health conditions studied

1

Description of health condition studied
Myocardial Infarction

ICD-10 code
I21.3

ICD-10 code description
Acute transmural myocardial infarction of unspecified site

2

Description of health condition studied
Type 2 diabetes

ICD-10 code
E11.9

ICD-10 code description
Type 2 diabetes mellitus without complications

Primary outcomes

1

Description

Galectin-3 gene expression

Timepoint

Measurement of Galectin-3 gene expression at the beginning of the study (before intervention) and 3 months after starting empagliflozin

Method of measurement

RT-PCR

2

Description

sST2 gene expression

Timepoint

Measurement of sST2 gene expression at the beginning of the study (before intervention) and 3 months after starting empagliflozin

Method of measurement

RT-PCR

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, 30 type 2 diabetic patients treated with oral drugs, and they will receive empagliflozin from ABIDI Pharmaceutical Company in the form of 10 mg tablets, once a day orally for 3 months.

Category

Treatment - Drugs

2

Description

Control group: In this group, 30 type 2 diabetic patients treated with oral drugs, and they will receive placebo made by ABIDI Pharmaceutical Company, once a day orally for 3 months.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital

Full name of responsible person

Mahnaz Yousefi Ramandi

Street address

Gavazang Road, Ayatollah Mousavi Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Habib Zayghami

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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

Zanjan University of Medical Sciences

Proportion provided by this source

15

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 Pharmaceutical Company

Full name of responsible person

Seyed Amir Razavian Ardehali

Street address

No. 72, Abidi Blvd., Kilometer 8 of Shahid Lashkari Highway

City

Tehran
Province
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1389776363
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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
Abidi Pharmaceutical Company
Proportion provided by this source
10
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Mahnaz Yousefi Ramandi
Position
Resident
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Other areas of specialty/work
Cardiology
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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
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Not applicable
Analytic Code
Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

The study protocol, statistical analysis plan and informed consent form will be shared with details.

When the data will become available and for how long

From the time of publication the results up to 3 months

To whom data/document is available

Academic institutions researchers

Under which criteria data/document could be used

Expansion of the research sample size

From where data/document is obtainable

Mahnaz Yousefi Ramandi mahnaz.yousefi70@gmail.com
00989128833831

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

The applicant must provide his/her documentary academic profile with the study plan and valid code of ethics to receive the data of this study.

Comments