Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

To Study the effect of Empagliflozin on the Incidence of short-term major Cardiovascular events in type 2 diabetic patients with myocardial infarction requiring primary angioplasty

Protocol summary

Study aim

Evaluation of the effect of ampagliflozin on the occurrence of short-term major cardiovascular events in type 2 diabetic patients with myocardial infarction requiring primary angioplasty in order to use it to prevent type 2 diabetic patients from developing cardiovascular events

Design

A clinical trial with a control and intervention group with parallel,double-blind, randomized phase 2 groups on 200 patients, ₩ill use the Rand function of Excel software for randomization..

Settings and conduct

The study will perform as a double-blind clinical trial in Mousavi Hospital in Zanjan. Patients were randomly admitted to the study according to the inclusion criteria so that neither the researcher nor the patient knew about the control and intervention groups. Medication and placebo are given to both groups for 3 months, and information on blood glucose levels and the incidence of cardiovascular events will review for up to 3 months.

Participants/Inclusion and exclusion criteria

Admission: Type 2 diabetic patients (treated with oral medications) - Diabetic patients with MI and previous treatment with metformin, sulfonylurea No entry: cardiogenic shock - Hypoglycemia -Diabetic ketoacidosis -History of coronary artery bypass surgery -Type 1 diabetes -Severe liver failure - Patients with advanced cancer -History of empagliflozin allergy - Hypovolemia - Severe renal failure -History of cancer - Any inflammatory disease under treatment -Advanced heart failure

Intervention groups

Evaluation of the efficacy of ampagliflozin on cardiovascular events after myocardial infarction in two groups of intervention (ampagliflozin recipient) and control (placebo recipient)

Main outcome variables

Short-term cardiovascular events after myocardial infarction such as death, heart failure, ventricular arrhythmia, readmission, re-infarction, stroke, myocardial infarction and the need for cardiopulmonary resuscitation.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210710051833N1**
Registration date: **2022-06-22, 1401/04/01**
Registration timing: **prospective**

Last update: **2022-06-22, 1401/04/01**
Update count: **0**

Registration date

2022-06-22, 1401/04/01

Registrant information

Name

Zahra Kalantari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3552 5654

Email address

zahra_kalantari88@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-23, 1401/05/01

Expected recruitment end date

2022-09-21, 1401/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

To Study the effect of Empagliflozin on the Incidence of short-term major Cardiovascular events in type 2 diabetic patients with myocardial infarction requiring primary angioplasty

Public title

Study the effect of Empagliflozin in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetic patients (treated with oral hypoglycemic drugs) with STEMI (typical chest pain lasting more than 30 minutes during the 12 hours prior to admission, with ST-segment elevation above 0.1 mV in both Lead or more on ECG) who will be admitted to Ayatollah Mousavi Hospital in Zanjan between August and October 1401 Diabetic patients with MI who have previously received prior treatment with metformin, sulfonylureas, or a combination of these two drugs.

Exclusion criteria:

Cardiogenic shock Hypoglycemia Diabetic ketoacidosis History of coronary artery bypass surgery Type 1 diabetes Severe liver failure Patients with advanced cancer History of severe hypersensitivity to empagliflozin or its components Severe renal failure (eGFR <30 mL / minute / 1.73 m2), end-stage renal disease (ESRD) or dialysis Hypovolemia Any inflammatory disease being treated History of any cancer Advanced heart failure

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be performed as a double blind clinical trial. In such a way that neither the researcher nor the patient knows which group will be treated with the drug or placebo, and the drug and the placebo will be provided to the patients by coding a third party (co-planner).

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

Azadi Blvd,Vice-Chancellor for Research and Technology

City

Zanjan

Province

Zanjan

Postal code

4515613191

Approval date

2021-10-21, 1400/07/29

Ethics committee reference number

IR.ZUMS.REC.1400.326

Health conditions studied

1

Description of health condition studied

Diabetes

ICD-10 code

E11.69

ICD-10 code description

Type 2 diabetes mellitus with other specified complication

2

Description of health condition studied

Heart disease

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mortality associated with cardiovascular events

Timepoint

Hospitalization time and one month and three months later

Method of measurement
Monthly face-to-face visits, tests and echoes

Secondary outcomes

1

Description
Ventricular arrhythmia
Timepoint
Three months after hospitalization and intervention
Method of measurement
Review of patient's hospital records during three months

2

Description
Re-infarction
Timepoint
Three months after hospitalization and intervention
Method of measurement
Review of patient's hospital records and echo

3

Description
Need for cardiopulmonary resuscitation
Timepoint
Three months after hospitalization and intervention
Method of measurement
Review of patient's hospital records during three months

4

Description
Congestive heart failure
Timepoint
Three months after hospitalization and intervention
Method of measurement
Review of patient's hospital records and echo

5

Description
Requires revascularization of target vessels
Timepoint
Three months after hospitalization and intervention
Method of measurement
Review of patient's hospital records during three months

6

Description
Stroke
Timepoint
Three months after hospitalization and intervention
Method of measurement
Review of patient's hospital records during three months

7

Description
Cardiogenic shock
Timepoint
Three months after hospitalization and intervention
Method of measurement
Review of patient's hospital records during three months

Intervention groups

1

Description
Intervention group Diabetic patients who presented with myocardial infarction and received 10 mg daily ampagliflozin tablets for three months.
Category
Treatment - Drugs

2

Description
Control group: Diabetic patients who presented with a heart attack and received a placebo daily for three months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Moosavi Hospital
Full name of responsible person
Zahra Kalantari
Street address
Moosavi Hospital, Prof. Sabouti Boulevard (Gavazang Road).
City
Zanjan
Province
Zanjan
Postal code
4513956183
Phone
+98 24 3313 0000
Fax
+98 24 3313 1203
Email
Zahra_kalantari88@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Zahra Meschi
Street address
Deputy of research and technology, Azadi Blvd
City

Zanjan
Province
Zanjan
Postal code
4515613191
Phone
+98 24 3315 6141
Fax
+98 24 3342 0460
Email
research@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
92
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
Industry

Person responsible for general inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Zahra Kalantari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
No. 18 , Azadegan Ave, Ahmadlo Blvd.
City
Zanjan
Province
Zanjan
Postal code
4513753111
Phone
+98 24 3552 5654
Fax
Email
Zahra_kalantari88@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Zahra Kalantari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
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Zanjan
Postal code
4513753111
Phone
+98 24 3552 5654
Fax
Email
Zahra_kalantari88@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
Zahra Kalantari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
No. 18 , Azadegan Ave.Ahmadlo Blvd.
City
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Province
Zanjan
Postal code
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Phone
+98 24 3552 5654
Fax
Email
Zahra_kalantari88@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be 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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Study data including (personal information, test results and outcomes) will be available in encrypted form in special forms designed to follow patients.

When the data will become available and for how long

The beginning of the data access period will be after the publication of the results in April 1402.

To whom data/document is available

Documentation will be available to researchers working in academic and scientific institutions. Access to data will be possible for people working in industry by fully introducing and clarifying the purpose of use.

Under which criteria data/document could be used

The use of data will be allowed only with the full introduction of researchers and clarification of the purposes of using the data and for use in future scientific issues and research.

From where data/document is obtainable

To access the data, you can contact Dr. Zahra Kalantari's researcher via e-mail Zahra_kalantari88@yahoo.com and work address (Zanjan, Gavazang Boulevard, Mousavi Hospital).

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

جهت دسترسی به داده ها پس از تماس با محقق از طریق ایمیا یا نشانی، پس از معرفی کامل فرد درخواست کننده و بیان هدف استفاده از داده ها، در طول مدت کمتر از یک ماه امکان دسترسی به داده ها وجود خواهد داشت.

Comments