

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparing the efficacy of empagliflozin versus dapagliflozin in the treatment of patients hospitalized with acute decompensated heart failure: A randomized active-controlled clinical trial

Protocol summary

Study aim

To compare the efficacy and safety of empagliflozin and dapagliflozin in the management of acute decompensated heart failure (ADHF).

Design

Prospective, open-label, randomized controlled trial enrolling 140 patients at Imam Khomeini Hospital, Tehran.

Settings and conduct

The study is conducted in the coronary care unit (CCU) and other cardiac wards, with patient screening in the emergency department and inpatient wards. Daily fluid intake, weight, and urine output are recorded. N-terminal pro-B-type natriuretic peptide (NT-proBNP) is measured at baseline and before discharge or on day 5. Spot urine electrolytes are measured at baseline and day 3. Congestion is assessed using the orthoedema scale at study start and end.

Participants/Inclusion and exclusion criteria

Patients aged ≥ 18 years with hypervolemic ADHF and an estimated glomerular filtration rate (eGFR) > 25 mL/min/1.73 m² are eligible. Exclusion criteria include serum glucose < 70 mg/dL, type 1 diabetes, history of diabetic ketoacidosis (DKA), systolic blood pressure < 90 mmHg, severe aortic or mitral stenosis, and acute coronary syndrome (ACS).

Intervention groups

Empagliflozin 10 mg once daily vs. dapagliflozin 10 mg once daily, both added to standard therapy.

Main outcome variables

The primary outcome is reduction in body weight at the end of the in-study period. Secondary Outcomes are 30-day mortality, 30-day readmission, change in NT-proBNP, and natriuresis measures. Safety outcomes include the incidence of acute kidney injury (AKI).

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240924063144N1**

Registration date: **2026-06-13, 1405/03/23**

Registration timing: **registered_while_recruiting**

Last update: **2026-06-13, 1405/03/23**

Update count: **0**

Registration date

2026-06-13, 1405/03/23

Registrant information

Name

Kasra Morad Soltani

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status recruiting

Funding source

Expected recruitment start date

2026-05-22, 1405/03/01

Expected recruitment end date

2026-09-20, 1405/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the efficacy of empagliflozin versus dapagliflozin in the treatment of patients hospitalized with acute decompensated heart failure: A randomized active-controlled clinical trial

Public title

Randomized clinical trial of empagliflozin vs dapagliflozin in acute decompensated heart failure.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 years or older Hospitalized for acute decompensated heart failure, defined as all of the following: (i) dyspnea at rest or with minimal exertion, (ii) signs of congestion, such as edema, rales, and/or congestion on chest radiograph, (iii) N-terminal pro BNP (NT-proBNP) ≥ 1400 pg/mL (for patients with atrial fibrillation: NT-proBNP ≥ 2000 pg/mL) Patients should be randomized within 24 hours and up to 5 days after hospitalization, as soon as possible after hemodynamic stabilization. Patients should have received at least one dose of intravenous furosemide at the time of screening. Patients should meet the following criteria for hemodynamic stabilization: (i) SBP ≥ 90 mm Hg and no signs of hypotension in the previous 6 hours (ii) Not receiving intravenous vasodilators in 6 hours before randomization (iii) Not receiving intravenous inotropes in 24 hours before randomization Consent to enter the study

Exclusion criteria:

Participation in other interventional clinical studies Serum glucose < 70 mg/dL Type 1 diabetes History of hypersensitivity to any SGLT-2 inhibitors Women who are pregnant or breastfeeding Severe anemia (Hemoglobin < 7 g/dL) Severe valvular disorders (Aortic stenosis and severe Mitral stenosis recognized based on guideline definitions and echocardiographic findings) and not associated with acute heart failure Severe hepatic impairment (Child-Pugh class C) Hospitalization due to acute coronary syndrome Shortness of breath (dyspnea) due to non-cardiac causes Cardiogenic shock Active urinary tract infection at the beginning of the study History of diabetic ketoacidosis and/or Hyperosmolar hyperglycemic state (pH < 7.30 and Plasma Glucose > 250 mg/dL and $\text{HCO}_3^- < 18$ mEq/L) Type 2 diabetic patients who receive high doses of insulin (more than 2 units/kg/day). eGFR < 25 ml/min/1.73m²

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomized to one of two groups: empagliflozin or dapagliflozin, using the block randomization size 4 method. Randomization will be based on a 1:1 ratio

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committee of institute of pharmaceutical sciences - Tehran university of medical sci

Street address

Central Building of Tehran University of Medical Sciences, 6th Floor, Room 604, Keshavarz Blvd., Quds St. Intersection, Tehran, Iran

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Province

Tehran

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1417614411

Approval date

2024-12-02, 1403/09/12

Ethics committee reference number

IR.TUMS.TIPS.REC.1403.164

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Heart failure

Primary outcomes

1

Description

Weight reduction at the end of the study

Timepoint

Measuring the patient's weight at the beginning of the study and then daily for 5 days or until discharge (whichever happens earlier).

Method of measurement

via weighing scale

Secondary outcomes**1****Description**

Furosemide efficacy.

Timepoint

At the end of the study (day 5) or discharge, whichever occurs first.

Method of measurement

$$\frac{\text{Weight on the fifth day} - \text{Weight on the first day}}{((\text{total dose of intravenous furosemide})/(40 \text{ mg}) + (\text{total dose of oral furosemide})/(80 \text{ mg}))}$$

2**Description**

Furosemide dose reduction.

Timepoint

The cumulative dose of furosemide (sum of intravenous and oral doses) will be measured daily and at the end of the study.

Method of measurement

Through the dose registration sheet.

3**Description**

Reducing the need to use inotropes.

Timepoint

Measured daily.

Method of measurement

Through the patient's file.

4**Description**

Reducing the need to use vasopressors.

Timepoint

Measured daily.

Method of measurement

Through the patient's file.

5**Description**

Reducing the need to add a second diuretic to the diuretic regimen.

Timepoint

Measured daily.

Method of measurement

Through the patient's file.

6**Description**

NT-proBNP changes.

Timepoint

Measured at enrollment of the study and on day five of the study or discharge, whichever occurs first.

Method of measurement

Lab test.

7**Description**

Serum creatinine changes.

Timepoint

Measured daily.

Method of measurement

Lab test.

8**Description**

Urine output changes.

Timepoint

Measured daily.

Method of measurement

Using urinary bag or collection container.

9**Description**

Orthoedema scale changes.

Timepoint

Measured at the baseline and on day five of the study or the day of hospital discharge (whichever occurs first).

Method of measurement

Using the Orthoedema scale.

10**Description**

Fractional Excretion of Sodium (FENa) changes.

Timepoint

Spot urine electrolytes will be measured at the patient's hospital admission and within 6 hours of receiving the IV furosemide dose, and also on the third day after receiving the studied medications.

Method of measurement

Using a spot urine sample and measuring the level of its electrolytes

11**Description**

Reducing the need for hemodialysis.

Timepoint

If hemodialysis is performed.

Method of measurement

Through the patient file.

12**Description**

Reducing 30-day mortality.

Timepoint

30 days after hospital discharge.

Method of measurement

Via telephone and medical record review.

13

Description

Reducing 30-day rehospitalization.

Timepoint

30 days after hospital discharge.

Method of measurement

Via telephone and medical record review.

14

Description

Reducing the length of hospital stay.

Timepoint

Measured as days from admission to discharge.

Method of measurement

Measured as days from admission to discharge.

15

Description

Incidence of acute kidney failure(AKI).

Timepoint

Evaluated daily.

Method of measurement

Based on the Kidney Disease: Improving Global Outcomes (KDIGO) criteria and through the monitoring of the patient's urine volume and serum creatinine.

16

Description

Incidence of Diabetic ketoacidosis.

Timepoint

Evaluated daily.

Method of measurement

Through monitoring venous blood gas, the presence of ketones in the urine sample, and the patient's blood sugar.

17

Description

Incidence of urinary tract infection.

Timepoint

Assessed daily for symptoms suggestive of urinary tract infection.

Method of measurement

Based on the treating physician's examination and history.

Intervention groups

1

Description

Intervention group 1: Empagliflozin 10 mg tablet from Actoverco Pharmaceutical Company, 1 tablet daily for 30 days.

Category

Treatment - Drugs

2

Description

Intervention group 2: Dapagliflozin 10 mg tablet from Actoverco Pharmaceutical Company, 1 tablet daily for 30 days.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Keyhan Mohammadi

Street address

At the end of Keshavarz Boulevard, Imam Khomeini Hospital Complex

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Keyhan Mohammadi

Street address

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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

Tehran 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**

Tehran University of Medical Sciences

Full name of responsible person

Keyhan Mohammadi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Clinical Pharmacy (Pharmacotherapy)

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Tehran University of Medical Sciences

Full name of responsible person

Kasra Morad Soltani

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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**Undecided - It is not yet known if there will be 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**Undecided - It is not yet known if there will be 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