Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

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 HCO3 < 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

City
Tehran

Province
Tehran

Postal code
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
(Weight on the fifth day - Weight on the first day)/((total dose of intravenous furosemide)/(40 mg) + (total dose of oral furosemide)/(80 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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Imamhospital@tums.ac.ir
Web page address
https://ikhc.tums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Keyhan Mohammadi
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Deputy of Research and Technology, 6th Floor, corner of Ghods Street, Central Office of the University, Keshavarz Boulevard
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Postal code
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Phone
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Email
vcr@tums.ac.ir
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
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Resident
Latest degree
Medical doctor
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kasraa.ms@gmail.com

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