# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

22 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**

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Iran (Islamic Republic of)

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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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## Sponsors / Funding sources

**1**

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**Full name of responsible person**
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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
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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