Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

A Study to Test Dapagliflozin in Patients with Acute Heart Failure

Protocol summary

Study aim
A Study to Test Dapagliflozin in Patients with Acute Heart Failure

Design
Patients with or without type 2 diabetes who are hospitalized with ADHF regardless of left ventricular ejection fraction (LVEF) will be randomly assigned to either to protocoled furosemide (40 mg intravenously) plus placebo or they will be received furosemide plus 10 mg of dapagliflozin daily. The duration of treatment will be 5 days in both groups; ejection fraction and serum level of sirtuin will be measured on day5. After that, patients in the control group will receive conventional treatments plus placebo, and in the test group, they will receive conventional treatments plus 10 mg dapagliflozin daily for 8 weeks. After the completion of the treatment, the patients of the two groups will be compared for amount of edema, heart function, serum level of BNP, urine volume, rate of referral to the cardiac care unit, and death.

Settings and conduct
A double-blind and randomized study which will be performed in Semnan Kowsar Hospital and Tehran Shahid Rajai Hospital.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients (age between 20-80 years) with acute decompensated heart failure (ADHF). Brain Natriuretic Peptide (BNP) >100 pg/ml, or N-terminal pro-BNP (NT-proBNP)>300 pg/ml with evidence of congestion Exclusion criteria: Type 1 diabetes Serum glucose < 80 mg/dL Systolic blood pressure < 90 mmHg Requirement of inotropic therapy History of hypersensitivity to SGLT-2 inhibitors Already receiving an SGLT2 inhibitor Pregnancy History of diabetic ketoacidosis Acute heart failure without signs of congestion ("dry" patient) Acute myocardial infarction

Intervention groups
Control group: IV furosemide plus placebo Intervention group: IV furosemide plus 10 mg oral dapagliflozin

Main outcome variables
Ejection fraction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20150617022794N3**
Registration date: **2024-06-09, 1403/03/20**
Registration timing: **prospective**

Last update: **2024-06-09, 1403/03/20**
Update count: **0**

Registration date
2024-06-09, 1403/03/20

Registrant information

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Bahador Bagheri

Name of organization / entity
Semnan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-07-05, 1403/04/15

Expected recruitment end date
2026-07-06, 1405/04/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A Study to Test Dapagliflozin in Patients with Acute Heart Failure

Public title
Dapagliflozin and acute heart failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Acute heart failure BNP>100 pg/ml receiving IV furosemide Evidence of congestion
Exclusion criteria:
Serum glucose < 80 mg/dL Type 1 diabetes mellitus Systolic blood pressure < 90 mmHg Requirement of inotropic therapy hypersensitivity to SGLT-2 inhibitors Already receiving an SGLT2 inhibitor Pregnancy History of DKA Acute MI
Age
From **20 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **200**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomly assigning people in two groups is permuted block randomization. In this method, A will represent group one (protocol treatment of furosemide with the addition of dapagliflozin 10 mg per day) and B will represent group two (furosemide plus placebo). In this way, the order of interventions A and B in the form of 5 blocks of 8 and 5 blocks of 12 from number 1 to 10 is determined by the methodological consultant of the project and placed at the disposal of the executive supervisor of the project.The executive supervisor selects one of the numbers 0 to 9 (1 to 9 blocks number 1 to 9 and zero is a sign for block number 10) using a table of random numbers, and then the qualified people according to the predetermined (from left to right) are attributed to one of two groups A or B. It should be mentioned in case of crossed consequences, another number (between 0 and 9) will be selected for such person.
Blinding (investigator's opinion)
Double blinded
Blinding description
After signing the consent letter, patients will be entered either in control or intervention group. Included patients are not aware of receiving placebo or the test drug. In addition, physicians and the department staff are blinded from patients allocation.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Semnan University of Medical Sciences
Street address
School of Medicine, Mashhad Road
City
Semnan
Province
Semnan
Postal code
3514799442
Approval date
2024-05-29, 1403/03/09
Ethics committee reference number
IR.SEMUMS.REC.1403.029

Health conditions studied

1

Description of health condition studied
Heart Failure
ICD-10 code
I50.0
ICD-10 code description
Systolic (congestive) heart failure

Primary outcomes

1

Description
ejection fraction
Timepoint
At admission and 5 days after receiving the medications and at study termination
Method of measurement
echocardiography

Secondary outcomes

1

Description
Serum level of Sirtuin-1
Timepoint
At admission and 5 days after receiving the medications
Method of measurement

ELISA

2

Description
Worsening of clinical conditions
Timepoint
At release till 8 weeks
Method of measurement
Readmission and phone call

Intervention groups

1

Description
Intervention group: 40 mg intravenous furosemide determined by amount of congestion. In addition, patients will receive 10 mg oral Dapagliflozin daily for 5 days (Kimia Pharmaceuticals). In case of patient release, dapagliflozin will be continued (10 mg, daily) for 8 weeks. Patients will be given other drugs according to conventional protocols.
Category
Treatment - Drugs

2

Description
Control group: Intravenous furosemide plus placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Kowsar Hospital
Full name of responsible person
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2

Recruitment center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Semnan 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
ShaRajaie Cardiovascular, Medical & Research Center
Full name of responsible person
Hooman Bakhshande
Position

Associate professor

Latest degree

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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