

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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 protocolled 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

Name

Bahador Bagheri

Name of organization / entity

Semnan University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 912 326 8059

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Recruitment status

recruiting

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

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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

Name of recruitment center

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Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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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

Ph.D.

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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