

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Evaluating the Efficacy of Oral Acetazolamide in Edema in Patients with Acute Decompensated Heart Failure: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Protocol summary

Study aim

Evaluating the effect of oral acetazolamide tablets on the severity of congestive heart failure in patients with acute decompensated heart failure.

Design

This study is a randomized, double-blind clinical trial controlled with placebo with a ratio of 1:1 on the diuretic and decongestion effects of oral acetazolamide in Iranian patients with acute decompensated heart failure (ADHF), which is conducted in phase three on 90 patients.

Settings and conduct

Place of study: Imam Khomeini Hospital; Study population: patients with acute decompensated heart failure; Type of blinding: double-blind; Blinding method: patients in the control group receive a placebo similar to acetazolamide tabs. The outcome evaluator and patients will not be aware of the type of intervention in the groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age over 18 years; diagnosis of ADHF with at least one sign of congestion; maintenance therapy with an oral loop diuretic; Use of SGLT2i; NT-proBNP more than 1000 ng/mL or BNP more than 250 ng/mL Exclusion criteria: Hospitalized due to acute coronary syndrome; history of congenital heart disease requiring surgery; Systolic blood pressure less than 90 mmHg or mean arterial pressure less than 65 mmHg; estimated glomerular filtration rate less than 20 mL/min/1.73 m²; Use of acetazolamide during hospitalization or prior to study entry; Use of diuretic medications except for mineralocorticoid antagonists and loop diuretics; Pregnant or breastfeeding women; Hyperchloremic metabolic acidosis

Intervention groups

The intervention group will receive acetazolamide 500 mg on day zero, then 250 mg BD for three days. The control group will receive placebo equivalent to

acetazolamide.

Main outcome variables

Decongestion and edema resolution

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250919067292N1**

Registration date: **2025-12-14, 1404/09/23**

Registration timing: **prospective**

Last update: **2025-12-14, 1404/09/23**

Update count: **0**

Registration date

2025-12-14, 1404/09/23

Registrant information

Name

Fatemeh Matin Farid

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

recruiting

Funding source

Expected recruitment start date

2025-12-22, 1404/10/01

Expected recruitment end date

2027-02-20, 1405/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluating the Efficacy of Oral Acetazolamide in Edema in Patients with Acute Decompensated Heart Failure: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Public title

Acetazolamide in edema in patients with Heart Failure

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Informed consent to participate in the study Age over 18 years Diagnosis of ADHF with at least one sign of congestion (such as edema, evidence of abdominal ascites on ultrasound, evidence of pulmonary edema on chest radiography or chest ultrasound) Maintenance therapy with an oral loop diuretic, at least 20 mg furosemide or 10 mg torsemide, one month prior to hospitalization Use of SGLT2i, including dapagliflozin and empagliflozin, for at least one month prior to hospitalization NT-proBNP more than 1000 ng/mL or BNP more than 250 ng/mL

Exclusion criteria:

Hospitalized due to Acute Coronary Syndrome History of congenital heart disease that requires surgery Systolic blood pressure less than 90 mmHg or mean arterial pressure less than 65 mmHg despite vasopressor administration Estimated glomerular filtration rate less than 20 mL/min/1.73m² Use of acetazolamide during hospitalization or prior to study entry Use of diuretic medications except for mineralocorticoid antagonists such as spironolactone and eplerenone and loop diuretics such as furosemide Pregnant or breastfeeding women Hyperchloremic metabolic acidosis

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be based on a 1:1 ratio to receive acetazolamide or placebo. The randomization list is generated using the block randomization method in 9 blocks of 10 by an online random number generator (www.sealedenvelop.com). Then, an independent pharmacist of the study will pack acetazolamide and placebo in sealed and numbered envelopes based on the

randomized list. The contents of the envelopes will be indistinguishable. The pharmacist evaluating the outcome will deliver the envelopes containing the drug or placebo to a nurse based on the randomization list to be given to the patients.

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo with the same shape, size, color, smell, and appearance as acetazolamide medication will be placed in sealed envelopes based on a randomization list generated by an independent pharmacist. The pharmacist evaluating outcome will be unaware of the contents of the envelopes and will deliver them to the nurses. Therefore, the study will be double-blinded, and the study participants and outcome assessor will be blinded to the study.

Placebo

Used

Assignment

Parallel

Other design features**Secondary ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

The Institute Of Pharmaceutical Sciences, Tehran University Of Medical Sciences

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Second Floor, The Institute Of Pharmaceutical Sciences, Tehran University Of Medical Sciences, 16 Azar Street, Enghelab Square

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Postal code

1417614411

Approval date

2025-09-16, 1404/06/25

Ethics committee reference number

IR.TUMS.TIPS.REC.1404.093

Health conditions studied**1****Description of health condition studied**

Acute decompensated heart failure

ICD-10 code

I50.4

ICD-10 code description

Combined systolic (congestive) and diastolic (congestive) heart failure

Primary outcomes

1

Description

Decongestion and edema resolution

Timepoint

Day zero at the beginning then daily for three days after randomization

Method of measurement

Clinical examination and recording congestion score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: They will receive acetazolamide 500 mg on day zero, then 250 mg twice daily for three days.

Category

Treatment - Drugs

2

Description

Control group: They will receive placebo equivalent to acetazolamide tablets in the intervention group on day zero and twice a day for three days. A placebo tablet with a similar appearance to acetazolamide 250 mg tablets (round white tablets), based on the registered formulation of acetazolamide tablets and similar excipients, without the active ingredient, has been designed and manufactured by Banyan Salamat Kasra (BSK) company.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Fatemeh Matinfarid

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Imam Khomeini Hospital, East Bagherkhan Street, East Chamran Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran 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

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

Somaye Mohammadi

Position

Assistant Professor of Heart failure

Latest degree

Subspecialist

Other areas of specialty/work

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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)

Yes - There is a plan to make this available

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

The patient characteristic data such as age, gender, and medications used, as well as information related to the primary and secondary outcomes of the intervention after de-identifying individuals.

When the data will become available and for how long

The beginning of access is after the conclusion of trial and the publication of results

To whom data/document is available

Access permission to academic and hospital researchers

Under which criteria data/document could be used

Statistical analysis

From where data/document is obtainable

1- Dr. Fateme Matinfarid fateme7.m.f80@gmail.com 2. Dr. Keyhan Mohammadi keyhanmohammadi72@yahoo.com 3. Dr SOMaye Mohammadi somayemohammadi.sm۶۱@gmail.com

What processes are involved for a request to access data/document

First, the applicant must send the documents they request access to, along with the reason and details, via email to the researchers of this project (provided in the previous box). After review and consultation, these documents will be sent to them.

Comments