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 m^2; 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 resolustion

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

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Name of organization / entity

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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
Street address
Second Floor, The Institute Of Pharmaceutical Sciences, Tehran University Of Medical Sciences, 16 Azar Street, Enghelab Square
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Province
Tehran
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 resolustion
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
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Sponsors / Funding sources

1

Sponsor
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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
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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. Fatemeh Matinfarid fatemeh7.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