Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jul 2026

Effect of 25 and 100 mg spironolactone on quality of life, ejection fraction and readmission in systolic heart failure patients with reduced ejection fraction in Imam Khomeini hospital in Ahvaz

Protocol summary

Study aim

Effect of 25 and 100 mg spironolactone on quality of life, ejection fraction and readmission in systolic heart failure patients with reduced ejection fraction in Imam Khomeini hospital in Ahvaz

Design

Clinical trial, parallel group trial with blinded, randomised outcome assessment, a phase 3 trial on 94 patients

Settings and conduct

The aim of the present study was to evaluate the effect of 25 and 100 mg spironolactone on quality of life, ejection fraction and readmission in systolic heart failure patients with reduced ejection fraction referred to Imam Khomeini Hospital in Ahvaz. Therapeutic effectiveness is measured by echocardiography, Minnesota Questionnaire and 6-MIN Walk test. This triple blind clinical trial is based on the protocol in which neither the participants, nor the researcher nor the data analyzer knows which treatment nor intervention participants are receiving until the clinical trial is over.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Acute systolic heart failure (EF <40) A history of hospitalization in the last 6 months Exclusion criteria: Known contraindications for spironolactone or prior documented intolerance to an aldosterone receptor antagonist Significant laboratory abnormalities (potassium ≥ 5.1 mmol) Mental disorders suspected to interact with study outcome Pregnant or nursing women Significant renal dysfunction Significant hypotension (lower than 90 mm Hg systolic or 60 mm Hg diastolic) CRT or ICD

Intervention groups

1- 25 mg spironolactone group daily for 6 months 2- 100 mg spironolactone group daily for 6 months

Main outcome variables

Quality of life; Ejection fraction; Readmission

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220404054403N1**
Registration date: **2022-05-30, 1401/03/09**
Registration timing: **prospective**

Last update: **2022-05-30, 1401/03/09**
Update count: **0**

Registration date

2022-05-30, 1401/03/09

Registrant information

Name

hossein lalvand

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3222 8037

Email address

hosseinlalvand69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-07-02, 1401/04/11

Expected recruitment end date

2022-10-08, 1401/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Effect of 25 and 100 mg spironolactone on quality of life, ejection fraction and readmission in systolic heart failure patients with reduced ejection fraction in Imam Khomeini hospital in Ahvaz

Public title
Effect of 25 and 100 mg spironolactone on quality of life, ejection fraction and readmission in systolic heart failure patients with reduced ejection fraction

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Acute systolic heart failure (EF <40) A history of hospitalization in the last 6 months

Exclusion criteria:
Known contraindications for spironolactone or prior documented intolerance to an aldosterone receptor antagonist Significant laboratory abnormalities (potassium ≥ 5.1 mmol) Mental disorders suspected to interact with study outcome Pregnant or nursing women Significant renal dysfunction Significant hypotension (lower than 90 mm Hg systolic or 60 mm Hg diastolic) CRT or ICD

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **94**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple, individual randomization with table of random numbers. Permuted randomization,Triple blind

Blinding (investigator's opinion)
Triple blinded

Blinding description
Blinding is based on the protocol in in which neither the participants, nor researcher nor the data analyzer knows which treatment or intervention participants are receiving until the clinical trial is over.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Golestan hospital

Street address
Farvardin Ave., Ahvaz., Iran

City
Ahvaz

Province
Khouzestan

Postal code
6135715794

Approval date
2022-03-08, 1400/12/17

Ethics committee reference number
IR.AJUMS.HGOLESTAN.REC.1401.003

Health conditions studied

1

Description of health condition studied
Systolic heart failure

ICD-10 code
I50.2

ICD-10 code description
Systolic (congestive) heart failure

Primary outcomes

1

Description
Ejection fraction

Timepoint
Before the intervention and 6 months after drug administration

Method of measurement
Echocardiography

2

Description
Quality of life

Timepoint
Before the intervention and 6 months after drug administration

Method of measurement
Minnesota Questionnaire

3

Description
Readmission

Timepoint
Before the intervention and 6 months after drug administration

Method of measurement
6 MIN Walk test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 25 mg spironolactone group daily for 6 months
Category
Treatment - Drugs

2

Description
Intervention group: 100 mg spironolactone group daily for 6 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini hospital
Full name of responsible person
Hossein Lalvand
Street address
Azadegan Ave., Ahvaz., Iran
City
Ahvaz
Province
Khouzestan
Postal code
6193673166
Phone
+98 61 3222 2922
Email
himam@ajums.ac.ir

2

Recruitment center
Name of recruitment center
Golestan hospital
Full name of responsible person
Hossein Lalvand
Street address
Farvardin Ave., Ahvaz., Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3320 4501
Email
golestanjpspital@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Deputy of research and technology
Street address
Esfand Ave., Golestan Blvd., Ahvaz., Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone
+98 61 3336 2414
Email
itc@ajums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Hossein Lalvand
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Cardiology
Street address
Esfand Ave., Golestan Blvd., Ahvaz., Iran
City
Ahvaz
Province
Khouzestan
Postal code
6135715794
Phone

+98 61 3222 8037

Email

hosseinlalvand69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Hossein Lalvand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

Esfand Ave., Golestan Blvd., Ahvaz., Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3222 8037

Email

hosseinlalvand69@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Hossein Lalvand

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Cardiology

Street address

Esfand Ave., Golestan Blvd., Ahvaz., Iran

City

Ahvaz

Province

Khouzestan

Postal code

6135715794

Phone

+98 61 3222 8037

Email

hosseinlalvand69@gmail.com

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