

# 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  $\geq$  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  $\geq$  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

Khuzestan

##### 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

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#### Province

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#### 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**

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## Person responsible for updating data

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**Name of organization / entity**

Ahvaz University of Medical Sciences

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Hossein Lalvand

**Position**

Resident

**Latest degree**

Medical doctor

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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