

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Effect of spironolactone with doses 25 and 50 mg in patients with symptomatic Systolic Heart Failure and Ejection Fraction less than 40% on quality of life and Ability and Readmission in 6 months

Protocol summary

2015-08-07, 1394/05/16

Summary

Purpose of study: to compare the therapeutic effects of spironolactone at a dose of 25 or 50 mg in patients with symptomatic systolic dysfunction with Ejection Fraction <40% on quality of life, Ejection Fraction and readmission, and the ability to work in a period of 6 months in hospital Methodology: Patients were divided into two groups of spironolactone 25 and 50 according to the exit and entry criteria. Each group consisted of 50 patients, and patients with symptomatic heart failure with Ejection Fraction less than 40 percent were the subject of the study. Spironolactone 25 was given to one group of patients and spironolactone 50 to the other group before discharge. Patients underwent echocardiography and 6MIN walk test and their quality of life questionnaires were completed; the tests were repeated 6 months later and the results of the two groups were compared. The potential side effects of spironolactone including increased BUN, CR, K were monitored during the study period and based on exclusion criteria cases with contraindications, renal failure, hypotension and hyperkalemia were excluded from the study. Specific objectives: Comparing Ejection Fraction, quality of life, readmission, and the ability to work in two groups of 25 and 50 mg spironolactone

Registrant information

Name

Khaled Hamid

Name of organization / entity

Ahwaz Jundishapur University of Medical Science

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahwaz Jundishapur University of Medical Science

Expected recruitment start date

2014-12-09, 1393/09/18

Expected recruitment end date

2015-08-01, 1394/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of spironolactone with doses 25 and 50 mg in patients with symptomatic Systolic Heart Failure and Ejection Fraction less than 40% on quality of life and Ability and Readmission in 6 months

Public title

Effect of Spironolactone in heart failure

Purpose

Treatment

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015010520563N1**

Registration date: **2015-08-07, 1394/05/16**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

Inclusion/Exclusion criteria

Inclusion criteria: patient with systolic heart failure : symptomatic : EF<40 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 women : Significant renal dysfunction (creatinine . 1.8 mg/dL) : Significant hypotension (blood pressure , 90 mmHg systolic and/or ,50 mmHg diastolic : CRT or ICD

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: 100

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahwaz Jundishapur University of Medical Science

Street address

Ahwaz , Golestan Highway

City

Ahwaz

Postal code

6135715794

Approval date

2015-04-11, 1394/01/22

Ethics committee reference number

IR.AJUMS.REC.1394.67

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

150.0

ICD-10 code description

congestive heart failure

Primary outcomes

1

Description

Ejection Fraction

Timepoint

At start of study and 6 month later

Method of measurement

Percent

2

Description

functional capacity

Timepoint

At start of study and 6 month later

Method of measurement

6 minute walk test { meter}

3

Description

Quality of life

Timepoint

At start of study and 6 month later

Method of measurement

Minesutta Quality of life qustionare{ score}

Secondary outcomes

1

Description

Cr

Timepoint

at start. after 3 month. after 6 month

Method of measurement

mg/dL

2

Description

potasium

Timepoint

at start. after 3 month. after 6 month

Method of measurement

mg/dL

3

Description

hypotansion

Timepoint

at start. after 3 month. after 6 month

Method of measurement

mmHG

Intervention groups

1

Description

one group of patients with a daily dose of 25 spironolactone tablets (control) for 6 months and all patients except spironolactone benefited from the same standard treatment for heart failure at discharge. The patients underwent echocardiography at admission with the VIVID 3 by echocardiography fellowship member. EF 2 C and 4 C were measured using SYMPSON. All the para-clinical data (echo, tests, ECG) of the patients were recorded at discharge and quality of life of all patients was assessed and recorded at discharge using Minesutta questionnaire. The questionnaire contained 21 questions, 8 of which concerned physical factors, 5 questions concerned emotional factors and 8 questions concerned other factors. The 21 questions has 105 points and each question and the responses varies from Very Able with 5 scores to Disable with score of zero. Moreover, patients in the rehabilitation ward underwent the 6 MIN walk test. In addition to routine tests and referrals after discharge patients are followed up based on AHA Guidelines in terms of their intention to treat and any incident such as death, not taking medicine, or not tolerating medicine. The telephone number of research team is given to patients and their family so that they call the team in case of any accident in the treatment process, or the need for readmission. As for the condition of electrolytes in spironolactone consumers, patients should be checked 3 and 7 days after the onset of renal function and then they are examined on a monthly basis according to clinical status and history of kidney problems. At the end of week 6 and 6 months electrolytes are checked and recorded. Finally, after 6 months patients undergo echocardiography with VIVID 3 by freshman fellowship and their quality of life was assessed by a questionnaire MINESUTTA. They again undergo 6 MIN walk test. At the end of the study, the percentage change in EF of patients

Category

Treatment - Drugs

2

Description

group of patients with a daily dose of 50 spironolactone tablets (case group) for 6 months and all patients except spironolactone benefited from the same standard treatment for heart failure at discharge. The patients underwent echocardiography at admission with the VIVID 3 by echocardiography fellowship member. EF 2 C and 4 C were measured using SYMPSON. All the para-clinical data (echo, tests, ECG) of the patients were recorded at discharge and quality of life of all patients was assessed and recorded at discharge using Minesutta questionnaire. The questionnaire contained 21 questions, 8 of which concerned physical factors, 5 questions concerned emotional factors and 8 questions concerned other factors. The 21 questions has 105 points and each question and the responses varies from Very Able with 5 scores to Disable with score of zero. Moreover, patients

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Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Khomeini Hospital

Full name of responsible person

Dr Khaled Hamid

Street address

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jundishapur University of Medical Science

Full name of responsible person

Research Center

Street address

Golestan Highway

City

Ahwaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahwaz Jundishapur University of Medical Science

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahwaz Jundishapur University of Medical Science

Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty