Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

Summary

Purpose of study: to compare the therapeutic effects of spirnolactone 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 spirnolactone 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. Spirnolactone 25 was given to one group of patients and spirnolactone 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

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

2015-08-07, 1394/05/16

Registrant information

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Khaled Hamid
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Ahwaz Jundishapur University of Medical Science
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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 Spirnolactone in heart failure

Purpose

Treatment

Inclusion/Exclusion criteria
Inclusion critria: patient with systolic heart failure ؛ symptomatic ؛ EF<40 EXCLUSION critria: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 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
Qulity of life
Timepoint
At start of study and 6 month later
Method of measurement
Minesutta Qulity 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 month 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 month 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

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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Fax

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Web page address

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