Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of spironolactone on the clinical characteristics, laboratory, and echocardiography in patients with heart failure Preserved EF

Protocol summary

Summary

In the patients with heart failure and preserved EF we will measure the effects of Spironolactone therapy on them based on clinical and laboratory findings and echocardiography to find out how it can help them to improve the quality of their life and to reduce in rehospitalization ,any complications and overall costs. This study is a prospective randomized double-blind clinical trial with placebo, phase 2, and single control center and will be done on 60 patients with symptomatic heart failure that have any EF equal to or greater than 45%, and required hospitalization in ICU. Exclusion criteria are serum creatinine > 2.5 mg/DLit in males and > 2 mg/DLit in females or GFR < 30ml/min/1.73 m2 and serum potassium> 5.5 mEq/L. Patients are divided randomly to two groups (based on the right first digit of national code): Intervention group (20 patients) and control group (40 patients). In the intervention group, we will start with 12.5 mg spironolactone tablets daily and if there is no increase in creatinine and potassium after two weeks it will be increased to 25 mg daily. The control group will receive placebo. In both groups we will check clinical characteristics and laboratory parameters (NT-proBNP, sodium, potassium, troponin, hemoglobin, creatinine, uric acid) five times (at the time of admission, 72 hours of hospitalization, at discharge, one month and three months after discharge).we will also check heart functional class and echocardiographic criteria (LA size, grade (DD), E / E ', E / A, PAP, RV size, MR (%), deceleration time, Tapse, EF) three times (at the time of admission, one month and three months after discharge) as well as length of stay in ICU, Acute Physiology and Chronic Health Evaluation 2 (APACHE II) score in the first 24 hours of hospitalization. Complications of spironolactone are checked too. All findings will be recorded properly.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101924597N1**
Registration date: **2016-01-29, 1394/11/09**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-01-29, 1394/11/09

Registrant information

Name
Saeid Soltaniomid
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2015-08-23, 1394/06/01

Expected recruitment end date

2016-04-19, 1395/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
The effect of spironolactone on the clinical characteristics, laboratory, and echocardiography in patients with heart failure Preserved EF

Public title
The effect of spironolactone in treatment of heart failure

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients have a clear history of heart failure, according to Framingham criteria (the two major criteria or a major criteria and two minor criteria); Transthoracic Echocardiography with an Ejection Fraction(EF) more than or equal to 45%; and based on the criteria in the class New York Heart Association(NYHA) III and IV and have need to admition in Intesive Care Unit(ICU). Exclusion criteria: serum creatinine > 2.5 mgr/dlit in males and > 2 mgr/dlit in females or GFR < 30ml/min/1.73 m2; serum potassium> 5.5 mEq/L.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
According to the right first digit of national code (odd or even) patients are divided into two groups(intervention group and control group)

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Hemmat Highway-Iran University of Medical Sciences

City
Tehran

Postal code

Approval date
2015-08-29, 1394/06/07

Ethics committee reference number
IR.IUMS.rec.1394.9311692001

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
NT-proBNP

Timepoint
At the time of admission, 72 hours of hospitalization, at discharge, one month and three months after discharge

Method of measurement
whole blood and FIA8000 Quantitative Immunoassay

2

Description
transthorasic ECHO: LA size، grade(DD)، E/E′، E/A، PAP، RV size، MR(%)، decleration time، Tapse، EF

Timepoint
At the time of admission , one month and three months after discharge

Method of measurement
ECHO

3

Description
Heart functional class

Timepoint
At the time of admission, one month and three months after discharge

Method of measurement
NYHA

4

Description
Laboratory parameters

Timepoint
At the time of admission, 72 hours of hospitalization, at discharge, one month and three months after discharge

Method of measurement
Creat. Hb. Tn. Na. U.A

Secondary outcomes

1

Description
The side effects of spironolactone
Timepoint
During treatment with spironolactone
Method of measurement
questionnaire

2

Description
APACHE II
Timepoint
In the first 24 hours of admission
Method of measurement
APACHE II score

3

Description
Length of stay in ICU
Timepoint
Length of stay in hospital
Method of measurement
The number of days of hospitalization in ICU

Intervention groups

1

Description
In the intervention group spironolactone tablets (tablets 25 mg pharmaceutical company Mino) at a dose of 12.5 mg daily after two weeks if there is no increase in creatinine and potassium is increased to 25 mg daily.
Category
Treatment - Drugs

2

Description
In the control group of spironolactone tablets that are quite similar to a placebo drug company is prepared
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hazrat Rasoul Hospital
Full name of responsible person
Dr.Saeid Soltaniomid
Street address
Hazrat Rasoul Hospital, Tehran
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research of Iran university of medical sciences
Full name of responsible person
Dr.Mehrdad Eftekhar
Street address
Hemmat Highway-Iran University of Medical Sciences
City
Tehran
Grant name
-
Grant code / Reference number
-
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research of Iran university of medical sciences
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
Iran University of Medical Sciences
Full name of responsible person
Dr.Saeid Soltaniomid
Position
Intensivist/ Executor of plan
Other areas of specialty/work
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Person responsible for scientific inquiries

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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