Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of spirinolactone and eplerenone on left ventricular systolic and diastolic function in patients with heart failure

Protocol summary

Study aim
Comparison between Eplerenone and Spironolactone in improving left ventricular systolic function among patients suffering from heart failure

Design
This single blind randomized clinical trial includes patients with symptomatic newly diagnosed heart failure without need to revascularization who take eplerenone or spironolactone, alternately in addition to taking usual heart failure medications. They undergo echocardiography at the beginning and then 6 months later and the alteration in echocardiographic variables will be compared between two groups.

Settings and conduct
This study is done on newly diagnosed symptomatic patients admitted to Fatemeh Zahra hospital in whom diagnosis of heart failure will be established based on the results of echocardiography.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Newly diagnosed symptomatic systolic heart failure patients; Exclusion criteria: Pregnancy, previous use of aldosterone antagonists, severe coronary artery disease with need to revascularization، hyperkalemia and serum creatinine more than 2mg/dl.

Intervention groups
Intervention group 1: These patients recieve oral spirinolactone tablet, 25 mg daily in addition to carvedilol and angiotensin converting enzyme inhibitor for 6 months, Intervention group 2: These patients recieve oral eplerenone tablet produced by Daroupakhsh company, 25 mg daily in addition to carvedilol and angiotensin converting enzyme inhibitor for 6 months.

Main outcome variables
The change in left ventricular systolic and diastolic function

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130422013090N4**
Registration date: **2019-06-27, 1398/04/06**
Registration timing: **registered_while_recruiting**

Last update: **2019-06-27, 1398/04/06**
Update count: **0**

Registration date
2019-06-27, 1398/04/06

Registrant information

Name
Maryam Nabati

Name of organization / entity
Mazandaran University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-01, 1398/03/11

Expected recruitment end date
2020-05-31, 1399/03/11

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of spirinolactone and eplerenone on left ventricular systolic and diastolic

function in patients with heart failure

Public title
Comparison between the effects of spironolactone and eplerenone in the treatment of heart failure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
New onset symptomatic systolic heart failure with left ventricular systolic ejection fraction less than 40%
Exclusion criteria:
Pregnancy Previous use of aldosterone antagonists Severe coronary artery disease with need to revascularization
Age
From **20 years** old to **90 years** old
Gender
Both

Phase
3
Groups that have been masked

- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will alternately be administered spirinolactone or eplerenone
Blinding (investigator's opinion)
Single blinded
Blinding description
The cardiologist who performs echocardiographic exams does not know which patients recieve spirinolactone and which ones recieve eplerenone.
Placebo
Not used
Assignment
Parallel
Other design features
All patients take carvedilol and angiotensin converting enzyme inhibitors.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mazandaran University of Medical Sciences
Street address
Deputy of Research Mazandaran University Of Medical Sciences, Moalem Square, Sari, Iran
City
Sari
Province
Mazandaran
Postal code
4818936897
Approval date
2019-05-04, 1398/02/14
Ethics committee reference number
IR.MAZUMS.REC.1398.362

Health conditions studied

1

Description of health condition studied
Systolic heart failure
ICD-10 code
I50.1
ICD-10 code description
Left ventricular failure

Primary outcomes

1

Description
Left ventricular ejection fraction
Timepoint
at the beginning of the study and 6 months after starting treatment
Method of measurement
Echocardiography

2

Description
global longitudinal systolic strain
Timepoint
at the beginning of the study and 6 months after starting treatment
Method of measurement
Echocardiography

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: These patients recieve oral spirinolactone tablet, 25 mg daily in addition to carvedilol and angiotensin converting enzyme inhibitor for 6 months.
Category
Treatment - Drugs

2

Description
Intervention group 2: These patients recieve oral eplerenone tablet produced by Daroupakhsh company, 25 mg daily in addition to carvedilol and angiotensin converting enzyme inhibitor for 6 months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sari Fatemeh Zahra hospital

Full name of responsible person
Maryam Nabati

Street address
Sari Training Building, Fatemeh Zahra Hospital, Artesh Blvd, Sari, Iran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mazandaran University of Medical Sciences

Full name of responsible person
Dr Majid Saeedi

Street address
Mazandaran University of Medical Sciences, Valiasr Highway, Juibar Crossroad, Imam Square, Sari, Iran

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Grant name

Grant code / Reference number

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

Title of funding source
Sari 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
Mazandaran University of Medical Sciences

Full name of responsible person
Maryam Nabati

Position
Associate professor of cardiology

Latest degree
Subspecialist

Other areas of specialty/work
Medical Education

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Position
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Person responsible for updating data

Contact

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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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable