

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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 receive oral spirinolactone tablet, 25 mg daily in addition to carvedilol and angiotensin converting enzyme inhibitor for 6 months, Intervention group 2: These patients receive 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

Country

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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 spironolactone or eplerenone

Blinding (investigator's opinion)

Single blinded

Blinding description

The cardiologist who performs echocardiographic exams does not know which patients receive spironolactone and which ones receive 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 receive oral spironolactone 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 receive 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

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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mazandaran University of Medical Sciences

Full name of responsible person

Dr Majid Saeedi

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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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Province

Mazandaran

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