

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

The study of the safety and effect of high dose allopurinol on the clinical, laboratory and echocardiographic variables in patients with severe left ventricle systolic dysfunction

Protocol summary

Summary

The aim of the study is to evaluate the safety and effect of high dose allopurinol on the clinical, laboratory and echocardiographic variables in patients with severe left ventricle systolic dysfunction. In this clinical trial study 30 patients referring to Rajaie cardiovascular medical and research center heart failure clinics from 18 to 80 years old who had severe heart failure and New York heart association functional class II-III and had informed consent for participating in the study were included. Patients must have had a complete optimal treatment for at least one month before entrance into the study. The diagnosis of severe left ventricular systolic dysfunction is according to the echocardiography done by a single echocardiologist and is defined as Left ventricle ejection fraction of less than 35%. The exclusion criteria are glomerular filtration rate of less than 60ml/min, gout, severe liver failure, patients without informed consent or those that have had sensitivity to allopurinol. Allopurinol is started with the dose of 600 mg daily in patients not taking it and increased to this dose in patients taking the medicine from before. The patients are observed for 3 three months. They have initial echocardiographic evaluation, strain imaging, laboratory testing and 6 minute walk test. And after 3 months they again have complete echocardiographic evaluation, strain imaging, laboratory testing and 6 minute walk test. The main adverse effects that will be noted are skin rashes and gastrointestinal problems.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015112125171N1**
Registration date: **2016-05-23, 1395/03/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-05-23, 1395/03/03

Registrant information

Name

Mohammad Mostafa Ansari Ramandi

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center,
Iran University of Medical Sciences, Tehran, Iran

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Recruitment status

Recruitment complete

Funding source

Rajaie cardiovascular medical and research center

Expected recruitment start date

2016-02-28, 1394/12/09

Expected recruitment end date

2016-03-06, 1394/12/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The study of the safety and effect of high dose allopurinol on the clinical, laboratory and

echocardiographic variables in patients with severe left ventricle systolic dysfunction

Public title

The study of the safety and effect of high dose allopurinol in patients with severe heart failure

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18-80 years old; severe left ventricle systolic dysfunction (Ejection fraction of less than 35%) on optimal medical treatment for at least one month with New York heart association functional class of II-III; having informed written consent. Exclusion criteria: Below the age of 18 and above the age of 80 years old; glomerular filtration rate of less than 60ml/min; serum creatinine level of more than 3mg/dl; severe hepatic failure; use of azathioprin; use of 6mercaptopurin; use of warfarin; known history of sensitivity to allopurinol.

Age

From **18 years** old to **80 years** old

Gender

Both

Phase

1-2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Rajaie Cardiovascular Medical and Research Center, Iran University of Medical Sciences, Tehran, Iran

Street address

Rajaie Cardiovascular Medical and Research Center, Tehran, Iran

City

Tehran

Postal code

Approval date

2016-02-27, 1394/12/08

Ethics committee reference number

RHC.AC.IR.REC.1394.35

Health conditions studied

1

Description of health condition studied

Heart failure

ICD-10 code

I50

ICD-10 code description

Primary outcomes

1

Description

ProBNP

Timepoint

3 month

Method of measurement

Laboratory kit

2

Description

6 minute walk test

Timepoint

3 month

Method of measurement

Rehabilitation department of the center

3

Description

Strain echocardiography

Timepoint

3 month

Method of measurement

Vivid 6s echocardiography system

4

Description

Quality of life of the patients

Timepoint

3 month

Method of measurement

IHF-QoL

Secondary outcomes

1

Description

Skin rash

Timepoint

during the 3 months

Method of measurement

Medical history and physical exam

2

Description

Gastrointestinal complications

Timepoint

during the 3 months

Method of measurement

Medical history and physical exam

Intervention groups

1

Description

Using 600 mg allopurinol daily for 3 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajaie Cardiovascular Medical and Research Center.
Tehran, Iran

Full name of responsible person

Mohammad Mostafa Ansari-Ramandi

Street address

Rajaie Cardiovascular Medical and Research Center.
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City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center,
Iran University of Medical Sciences, Tehran, Iran

Full name of responsible person

Majid Maleki

Street address

Rajaie Cardiovascular Medical and Research Center,
Tehran, 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

Rajaie Cardiovascular Medical and Research Center, Iran
University of Medical Sciences, Tehran, Iran

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

Rajaie Cardiovascular Medical and Research Center.
Tehran, Iran

Full name of responsible person

Mohammad Mostafa Ansari-Ramandi

Position

Cardiology resident

Other areas of specialty/work

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Full name of responsible person

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Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

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Full name of responsible person

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Position

Cardiology resident

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty