Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 clinic al, 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 gasterointestinal 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

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Name of organization / entity

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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 allopurino l 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 Cente, 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
150
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 compliations
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
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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
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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

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Person responsible for updating data

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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