

# 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 88233597

###### Email address

naderi@rhc.ac.ir

##### 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.  
Tehran, Iran

**City**

Tehran

**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

**City**

Tehran

**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**

**Street address**

Rajaie Cardiovascular Medical and Research Center.  
Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21 8823 3597

**Fax**

**Email**

dr\_mm\_ansari@yahoo.com

**Web page address**

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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

**Full name of responsible person**

Nasim Naderi

**Position**

Cardiologist, heart failure specialist

**Other areas of specialty/work**

**Street address**

Rajaie Cardiovascular Medical and Research Center,  
Tehran, Iran

**City**

Tehran

**Postal code**

**Phone**

+98 21 2392 2115

**Fax**

**Email**

dr\_mm\_ansari@yahoo.com

**Web page address**

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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

**Full name of responsible person**

Mohammad Mostafa Ansari-Ramandi

**Position**

Cardiology resident

**Other areas of specialty/work****Street address**

Rajaie Cardiovascular Medical and Research Center.  
Tehran, Iran

**City**

Tehran

**Postal code****Phone**

+98 21 8823 3597

**Fax****Email**

dr\_mm\_ansari@yahoo.com

**Web page address****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*