

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Investigating the effects of rosuvastatin in the acute cardiomyopathy induced anthracycline in cancer patients under chemotherapy

#### Protocol summary

2017-05-08, 1396/02/18

#### Summary

Objectives: This study aimed to assess the effectiveness of rosuvastatin in reducing the acute cardiomyopathy in the patients undergoing chemotherapy with anthracycline. Design: Randomized, clinical, single-blind, placebo-controlled, single-center, third-phase trial Main inclusion criteria: Cancerous patients undergoing treatment with anthracycline (doxorubicin) in Baghban Special Clinic in April 2016 to April 2017 include. Main exclusion criteria: Patients with history of myocardial infarction; coronary artery disease; patients in the early stages of chemotherapy or radiotherapy; acute restraint or dilated cardiomyopathy; mitral and aortic valvular diseases in initial echocardiography Sample size was calculate 100 people. Method: Patients will randomly located in control group (not receiving rosuvastatin) and rosuvastatin group (receiving rosuvastatin). Studied interventions: In rosuvastatin, 20 mg rosuvastatin use per day before camotherapy up to 6 months. The control group also uses the placebo. The placebo has a similar dose to rosuvastatin (20 mg per day). Main outcome variables: Diastolic and systolic diameter and volume, and ejection fraction of left ventricular and mitral inflow with Doppler pulse (E, A, wave, E/A wave, E-wave deceleration time), and pulmonary venous flow, and Doppler tissue, mitral annulus, E/é ratio are calculated.

#### Registrant information

##### Name

Maryam Nabati

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 15 1222 4002

##### Email address

m.nabati@mazums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Mazandaran University Of Medical Sciences

#### Expected recruitment start date

2017-01-20, 1395/11/01

#### Expected recruitment end date

2018-04-05, 1397/01/16

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Investigating the effects of rosuvastatin in the acute cardiomyopathy induced anthracycline in cancer patients under chemotherapy

#### Public title

A clinical trial to investigate the efficiency of rosuvastatin in acute cardiomyopathy induced anthracycline

#### Purpose

Prevention

#### Inclusion/Exclusion criteria

Inclusion criteria: Cancerous patients undergoing

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016121213090N3**

Registration date: **2017-05-08, 1396/02/18**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

treatment with anthracycline Exclusion criteria: Patients with history of myocardial infarction; coronary artery disease; patients in the early stages of chemotherapy or radiotherapy; acute restraint or dilated cardiomyopathy; mitral and aortic valvular diseases in initial echocardiography; patients with a history or any symptoms associated with heart failure; hypersensitivity to rosuvastatin; active liver diseases; and impaired liver tests; pregnant and lactating women.

#### Age

From **18 years** old to **60 years** old

#### Gender

Both

#### Phase

3

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **80**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Single blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

Study randomization method is four blocks.

## 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

##### Postal code

#### Approval date

2016-12-21, 1395/10/01

#### Ethics committee reference number

IR.MAZUMS.REC.95.2211

## Health conditions studied

### 1

#### Description of health condition studied

Cardiomyopathy

#### ICD-10 code

I42

#### ICD-10 code description

Cardiomyopathy

## Primary outcomes

### 1

#### Description

triglycerides level

#### Timepoint

0 and 6 month

#### Method of measurement

mg/dl

## Secondary outcomes

### 1

#### Description

left ventricle ejection fraction

#### Timepoint

percent

#### Method of measurement

echocardiography

## Intervention groups

### 1

#### Description

Intervention group: Rosuvastatin, 20 mg oral pill (by Fanda Pharmaceutical Co.) per day for six months

#### Category

Treatment - Drugs

### 2

#### Description

Control group: placebo, 20 mg oral pill (by School of Pharmacy, Mazandaran University of Medical Sciences) per day for six months

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Fatemeh Zahra Hospital Of Sari

##### Full name of responsible person

Jamil Esmailian

##### Street address

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

##### City

Sari

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Vice chancellor for research of Mazandaran University of Medical Sciences

**Full name of responsible person**

Ahmad Ali Enayati

**Street address**

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

**City**

Sari

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research of Mazandaran University of Medical Sciences

**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**

Student Research Committee, Mazandaran University Of Medical Sciences

**Full name of responsible person**

Jamil Esmailian

**Position**

Residency Of Cardiology

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

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## Person responsible for scientific

## inquiries

**Contact****Name of organization / entity**

Mazandaran University Of Medical Sciences

**Full name of responsible person**

Maryam Nabati

**Position**

Assistant Professor Of Cardiology

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## Person responsible for updating data

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**Full name of responsible person**

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**Position**

Residency of Cardiology

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

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

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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*