

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

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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

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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

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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