

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Efficiency of carvedilol in the protection of Anthracycline-induced cardiomyopathy in cancer patients undergoing chemotherapy compared with control group

Protocol summary

Summary

This study is a sequential single blind randomized trial on 18-70 years age, new diagnosed cancer patients that should undergo antracyclin therapy. Written informed consent are obtained from all patients. Before initiation of chemotherapy, all patients undergo echocardiography by Vivid S5 and the images are stored for off line analysis. Left ventricular end diastole and end systole diameters are measured and LVEF is calculated by Simpson method. Evaluation for diastolic function is performed by mitral inflow evaluation: pulse doppler (E,A wave, E/A ratio, E wave deceleration time), pulmonary veins flow and tissue doppler of mitral valve annulus. E/e' ratio is calculated for determination of filling pressure. Patients are inserted randomly in control(no carvedilol)and intervention(carvedilol)groups. Age,sex and other variables are similar in two groups. In the intervention group, carvedilol is initiated at least 24 hours before first cycle of chemotherapy. Initial dose is 3.12mg BID(in patients with systolic blood pressure more than 90-100mmHg). Dose is gradually increased after one week. If systolic blood pressure is more than 90 mmHg , maximum dose is increased to 6.25mg BID. Patients in intervention group are evaluated for hypotension, bradycardia and etc. If hypotension occurs, carvedilol is decreased or stopped. If systolic blood pressure increased, it is again initiated. All patients receive chemotherapy according to protocol. One month later,cardiac Troponin I is measured. Then, in the terminal part of follow up, after 6months, patients undergo echocardiography that echocardiographer is blinded. Two groups are compared for change in left ventricular systolic and diastolic performance and Troponin levels.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014121213090N2**
Registration date: **2015-01-09, 1393/10/19**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-01-09, 1393/10/19

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

2015-01-30, 1393/11/10

Expected recruitment end date

2016-01-30, 1394/11/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficiency of carvedilol in the protection of Anthracycline-induced cardiomyopathy in cancer patients undergoing chemotherapy compared with control group

Public title

Efficiency of carvedilol in the protection of Anthracycline-induced cardiomyopathy in cancer patients undergoing chemotherapy compared with control group

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Cancer patients; 18-70 years old; newly diagnosed; candidate for antracyclin therapy. Exclusion criteria: history of myocardial infarction; coronary artery disease; LVEF<50%; significant valvular heart disease; history of congestive heart failure; sinus bradycardia, complete heart block, systolic blood pressure less than 90 mmHg.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mazandaran University of Medical Sciences Ethics Committee

Street address

Mazandaran University of Medical Sciences

City

Sari

Postal code

Approval date

2014-11-19, 1393/08/28

Ethics committee reference number

28 8 2014

Health conditions studied

1

Description of health condition studied

Cancer

ICD-10 code

C00-C97

ICD-10 code description

Malignant Neoplasms

Primary outcomes

1

Description

Cardiomyopathy

Timepoint

Before treatment,6 months later

Method of measurement

Echocardiography

Secondary outcomes

1

Description

Level of cardiac Troponin-I

Timepoint

One month after treatment

Method of measurement

Venopuncture

Intervention groups

1

Description

In case group,at least 24 hours before chemotherapy,carvedilol 3.12- 6.25mg BID is initiated and continued till termination of chemotherapy.

Category

Treatment - Drugs

2

Description

Control group receive chemotherapy drug alone.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Toba clinic

Full name of responsible person

Maryam Nabati

Street address

Khazar square

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

Dr Ahmadali Enayati

Street address

Moallem square

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**

Mazandaran University of Medical Sciences

Full name of responsible person

Maryam Nabati

Position

Cardiologist, Fellowship of Echocardiography

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

Fateme Zahra Hospital, Shahr-dari Square

City

Sari

Postal code**Phone**

+98 11 3332 4002

Fax**Email**

dr.mr.nabati@gmail.com

Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Maryam Nabati

Position

Cardiologist, Fellowship of Echocardiography

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

Fateme Zahra Hospital, Shahr-dari Square

City

Sari

Postal code**Phone**

+98 11 3332 4002

Fax**Email**

dr.mr.nabati@gmail.com

Web page address**Person responsible for updating data****Contact****Name of organization / entity**

Mazandaran University of Medical Sciences

Full name of responsible person

Maryam Nabati

Position

Cardiologist, Fellowship of Echocardiography

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

Fateme Zahra Hospital

City

Sari

Postal code

48188-13771

Phone

+98 11 3332 4002

Fax

+98 11 3332 4002

Email

Dr.mr.nabati@gmail.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