Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jun 2026

Efficiency of enalapril in the protection of Anthracycline-induced cardiomyophy in cancer patients undergoing chemotheraphy compared with control group in Toba clinic in 2013-2014

Protocol summary

Summary

This study is a sequential single blind-matched randomized trial on 18-70 years age new diagnosed patients that should be underwent antracyclin therapy in Toba clinic, Sari, Iran in 2013-2014. Written informed consent was obtained from all patients. Before initiation of chemotherapy, all patients underwent 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 alternately in control(no Enalapril)and intervention(Enalapril)groups. Age,sex and other variables are similar in two groups. In the intervention group, Enalapril is initiated at least 24 hours before first cycle of chemotherapy. Initial dose is 2.5mg BID(1.25mg in patients with systolic blood pressure up to 90-100mmHg). Dose is gradually increased each 3-6 days. If systolic blood pressure is more than 90 mmHg and serum creatinine is less than 2.5mg/dl, maximum dose is increased to 5-10mg BID. Patients in intervention group are evaluated for gasterointestinal side effects, skin rashs, cough and etc. If hypotension occurs, Enalapril is decreased or stopped. systolic blood pressure increased, again it is 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 6-9 months, patients underwent echocardiography. Two groups are compared for change in left ventricular systolic and diastolic performance and Troponin levels. Quantitative variables in baseline and terminal part of study are calculated by paired t test in each group.Two group are compared by independent t test. All data are analyzed by SPSS software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013042213090N1**
Registration date: **2013-06-03, 1392/03/13**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2013-06-03, 1392/03/13

Registrant information

Name

Maryam Nabati

Name of organization / entity

Mazandaran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 15 1222 4002

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2013-05-05, 1392/02/15

Expected recruitment end date

2014-05-05, 1393/02/15

Actual recruitment start date

empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Efficiency of enalapril in the protection of Anthracycline-induced cardiomyophy in cancer patients undergoing chemotheraphy compared with control group in Toba clinic in 2013-2014

Public title
Efficiency of enalapril in the protection of Anthracycline-induced cardiomyophy in cancer patients undergoing chemotheraphy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: patients aged between 18-70 years old; new diagnosed cancer patients that should be underwent antracyclin therapy. Exclusion criteria: history of myocardial infarction or coronary artery disease; LVEF<50%; significant valvular heart disease; history of congestive heart failure; renal failure with glomerular filteration rate of less than 30ml/h; history of allergy to ACEI and 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:
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, Moallem square
City
Sari
Postal code
4817844718
Approval date
2013-01-23, 1391/11/04
Ethics committee reference number
91-185

Health conditions studied

1

Description of health condition studied
Cancer
ICD-10 code
COO-D48
ICD-10 code description
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 casel group,atleast 24 hours before chemotherapy,enalapril 5-10mg BID is initiatatad 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
Dr Maryam Nabati
Street address
Fateme Zahra hospital, Shahrdari Square
City
Sari

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Mazandaran University of Medical Sciences
Full name of responsible person
Dr Mohammadreza Haghshenas
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, 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
Dr Maryam Nabati
Position
Cardiologist, fellowship of echocardiography
Other areas of specialty/work
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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