

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

17 Jun 2026

### Efficiency of enalapril in the protection of Anthracycline-induced cardiomyopathy in cancer patients undergoing chemotherapy 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 anthracyclin 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 rashes, 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

##### Email address

m.nabati@mazums.ac.ir

##### 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 cardiomyopathy in cancer patients undergoing chemotherapy compared with control group in Toba clinic in 2013-2014

**Public title**

Efficiency of enalapril in the protection of Anthracycline-induced cardiomyopathy in cancer patients undergoing chemotherapy

**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 filtration 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 initiatedad 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, Shahr-dari 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**

**Street address**

Fateme Zahra hospital, Shahr-dari Square

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4815733971

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**Email**

Dr.mr.nabati@gmail.com

**Web page address**

http://mazums.ac.ir

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Mazandaran University of Medical Sciences

**Full name of responsible person**

Dr Maryam Nabati

**Position**

Cardiologist, fellowship of echocardiography

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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*