

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Protective effects of Bisoprolol against anthracycline-induced cardiomyopathy in breast cancer patient

Protocol summary

Study aim

Evaluation of protective effects of bisoprolol against anthracycline-induced cardiomyopathy

Design

In this randomized double-blind study, which is a trial phase 3, We enroll 90 patients with breast cancer recommended for treatment with adriamycin and cyclophosphamide. Patients randomly bisoprolol (n = 45) and placebo (n = 45) daily. Excel software rand function is used for randomization.

Settings and conduct

Prophylactic use of bisoprolol for reducing cardiomyopathy induced by anthracycline is the field of study that done in Shariati hospital. We identify breast cancer patients who are candidates for anthracycline chemotherapy. In the intervention group, bisoprolol is administered orally at a dose of 2.5 mg and also placebo in the control group for 7 consecutive days before chemotherapy in the morning. Both bisoprolol and placebo last for 6 months. Echocardiography is performed at the beginning, three and 6 months after chemotherapy. The data is analyzed. The data collection and analysis stage, will be done by the project manager. The patient, the executor of the plan & supervisor, are not aware of the contents of the packages. This study is two-blinded.

Participants/Inclusion and exclusion criteria

Inclusion: 1. Patients with breast cancer 2. Patients treated with anthracyclines 3. Patients who do not have chronic blood pressure, diabetes Exclusion: 1. Patient dissatisfaction 2. A patient who has a contraindication to the use of beta-blockers 3. History of radiation or chemotherapy to the chest 4. Receiving beta-blocker drugs

Intervention groups

the intervention group, bisoprolol administer at a dose of 2.5 mg and in the control group, placebo administer orally for 7 consecutive days before chemotherapy in the morning & continues for 6 months.

Main outcome variables

left ventricular end diastolic & systolic volume/left ventricular end diastolic & systolic diameter/global longitudinal strain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130701013828N8**

Registration date: **2021-10-04, 1400/07/12**

Registration timing: **prospective**

Last update: **2021-10-04, 1400/07/12**

Update count: **0**

Registration date

2021-10-04, 1400/07/12

Registrant information

Name

Ahmad Mirdamadi

Name of organization / entity

Islamic Azad university, Najafabad branch

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-23, 1400/08/01

Expected recruitment end date

2022-03-20, 1400/12/29

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Protective effects of Bisoprolol against anthracycline-induced cardiomyopathy in breast cancer patient

Public title
Protective effects of Bisoprolol against anthracycline-induced cardiomyopathy in breast cancer patient

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
 Patients with breast cancer Patients with indication for AC (doxorubicin hydrochloride (Adriamycin) and cyclophosphamide) regimen for chemotherapy Patients agreement
Exclusion criteria:
 Patients non compliance Patients who have cardiovascular problems Have previously undergone chest radiotherapy Patients who have allergy to Bisoprolol Patients currently taking beta-blockers Patients who have contraindicated for use beta blockers.

Age
From **25 years** old to **75 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
 Target sample size: **90**
 More than 1 sample in each individual
 Number of samples in each individual: **45**
 In intervention group 45 individuals and in control group 45 individuals become participate.

Randomization (investigator's opinion)
Randomized

Randomization description
 In this study use block randomization and unit of randomization is individual. Block randomization divides patients into M blocks of size 2N, so that in each block N patients are assigned A and patients N are assigned to B. The block is then selected randomly. The size of the block is not stated in the study so that researchers are blind to it. Rand Excel function randomization tool is helpful.

Blinding (investigator's opinion)
Double blinded

Blinding description
 Patients are treated with medication packages pre-determined by the study supervisor. Drug packages are exactly the same in shape and the patient and the

project facilitator are not aware of the contents of the packages. The executor and his assistant are done who are not aware of the contents of the packages; In the data analysis stage, the analysis will be performed by the project consultant and the project manager who are not aware of the contents of the drug packages and only the group of patients (group 1 or 2) will be identified for data analysis; Therefore, the study is three-blind and the contents of the two drug groups are not clear from the stage of patient entry into the study to the study, data collection and analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Isfahan University of Medical Sciences
Street address
School of Medicine ,Isfahan University,Azad Square, Isfahan
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Province
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Postal code
8174673441
Approval date
2021-06-22, 1400/04/01
Ethics committee reference number
IR.IAU.NAJAFABAD.REC.1400.058

Health conditions studied

1

Description of health condition studied
chemotherapy induced cardiomyopathy in breast cancer patients
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
LVEDV(left ventricular end diastolic volume)
Timepoint
 The first measurement is before the start of chemotherapy and before the intervention, then three months and six months after chemotherapy and during

the intervention.

Method of measurement

Specialized echocardiography

2

Description

(GLS)global longitudinal strain

Timepoint

The first measurement is before the start of chemotherapy and before the intervention, then three months and six months after chemotherapy and during the intervention.

Method of measurement

Specialized echocardiography

3

Description

LVESD(left ventricular end systolic diameter)

Timepoint

The first measurement is before the start of chemotherapy and before the intervention, then three months and six months after chemotherapy and during the intervention.

Method of measurement

Specialized echocardiography

4

Description

LVEDD(left ventricular end diastolic diameter)

Timepoint

The first measurement is before the start of chemotherapy and before the intervention, then three months and six months after chemotherapy and during the intervention.

Method of measurement

Specialized echocardiography

5

Description

LVESV(left ventricular end systolic volume)

Timepoint

The first measurement is before the start of chemotherapy and before the intervention, then three months and six months after chemotherapy and during the intervention.

Method of measurement

Specialized echocardiography

Secondary outcomes

1

Description

cardiotoxicity

Timepoint

before chemotherapy and end of chemotherapy

Method of measurement

Echocardiography

2

Description

Dizziness

Timepoint

after start of drug

Method of measurement

Ask patient

Intervention groups

1

Description

Intervention group: 2.5 mg Bisoprolol tablets from Abidi company are taken daily from one week before the start of chemotherapy until the end of the chemotherapy course

Category

Prevention

2

Description

Control group: Placebo is given to the control group like intervention group from one week before the start of chemotherapy until the end of the chemotherapy course

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr khosravis private office

Full name of responsible person

Dr mohammad reza khosravi farsani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Ahmad Mirdamadi

Position
Cardiologist,Fellowship of Echocardiography
/Assistant Professor of medical school

Latest degree
Specialist

Other areas of specialty/work
Cardiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to
make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available