Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Determining the Preventive Effect of Carvedilol on Reducing Transtosomab Cardiac Complications in Patients With Early Stages of HER2-Breast Cancer

Protocol summary

Study aim
Determining the preventive effect of Carvedilol on reducing Trastuzumab cardiac complications in patients with early stages of HER2-Breast cancer

Design
Clinical trial phase3 two groups(30-30) parallel, outcome assessor blinded

Settings and conduct
60 patients with primary breast cancer who are candidates for chemo-therapy with Adrenocorticotropic hormone (AC-TH) are underway at the Department of Oncology at Sina Hospital, will be randomly divided into intervention and control groups. Carvdilol 3,125 mg twice daily in the intervention group lasts for about one year during the adjuvant treatment with herceptin. Basic echocardiography (after the end of the anthracycline regimen) and then at the end of sessions 4, 8, 12, and one month after the end of Herceptin treatment regimen will be used to evaluate the Ejection Fraction (EF).

Participants/Inclusion and exclusion criteria
Inclusion criteria: recently diagnosed breast cancer with early stages and eligible for adjuvant treatment with trastuzumab Exclusion: History of heart diseases, Contraindication of treatment with or receiving beta-blocker drugs; uncontrolled blood pressure; history of radiotherapy or chemotherapy to the chest; renal disorder

Intervention groups
Intervention group: taking Carvedilol Comparison group: not taking Carvedilol (routine care)

Main outcome variables
left ventricular ejection fraction (LVEF) Metastases

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190628044046N1**
Registration date: **2020-03-12, 1398/12/22**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-12, 1398/12/22**
Update count: **0**

Registration date
2020-03-12, 1398/12/22

Registrant information

Name
Mina Naderi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 7786 5654

Email address
mina.naderi89@icloud.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-06-26, 1398/04/05

Expected recruitment end date
2020-08-20, 1399/05/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Determining the Preventive Effect of Carvedilol on Reducing Transtosomab Cardiac Complications in

Patients With Early Stages of HER2-Breast Cancer

Public title
Effect of Carvedilol on Reducing Transtosomab Cardiac Complications
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients who have recently been diagnosed with breast cancer (HER2-overexpressing) (stage I to IIIA) and are candidates for adjuvant treatment with trastuzumab. The ability to have an informed consent.
Exclusion criteria:
Left Ventricular Ejection Fraction (LVEF) baseline less than 50%, history of heart failure. Contraindication of treatment with or receiving drugs for beta blocker(BB). cardiomyopathy or valvular heart disease, myocardial infarction, uncontrolled blood pressure. history of radiotherapy or chest chemotherapy to the chest. filtration Glomerular volume 30 mL / min / 1.73 m2, which is calculated using the Modification of Diet in Renal Disease (MDRD)method.
Age
No age limit
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple individual randomization, without stratification, produced by Excel (Microsoft office) (using "Generate random number" order and "if") and providing a table of A(intervention) and B(control) sequence. # =randbetween(1-60) #save as "value" #copy for 60 rows # =if (A1>MEDIAN(A1:A60), 1,0) #copy for 60 rows #Replace "1" by "A"in all #Replace "0" by "B"in all
Blinding (investigator's opinion)
Single blinded
Blinding description
The main outcome(LVEF) assessor(Echo-man) is not aware of intervention groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee in Research-Emam Khomeini hospital complex-Tehran Unversity of Medical Sciences
Street address
Emam Khomeini hospital complex- Keshavarz Ave-Gharib street
City
Tehran
Province
Tehran
Postal code
۱۴۱۹۷۳۳۱۴۱
Approval date
2019-06-24, 1398/04/03
Ethics committee reference number
IR.TUMS.IKHC.REC.1398.086

Health conditions studied

1

Description of health condition studied
Trastuzumab related cardiomyopathy
ICD-10 code
I50.1
ICD-10 code description
Left ventricular failure

Primary outcomes

1

Description
left ventricular ejection fraction
Timepoint
The end of the anthracycline chemotherapy and then the end of sessions 4, 8, 12 and one month after the end of Herceptin
Method of measurement
Echocardiography

2

Description
Metastasis
Timepoint
At the end of follow up
Method of measurement
تصویربرداری

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Carvedilol drug with 3.125 mg twice daily and then increasing the dose weekly up to 12.5 mg or up to the tolerance
Category
Prevention

2

Description
Control group: Not taking Carvedilol (Routine care)
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Sina hospital
Full name of responsible person
Mina Naderi
Street address
Imam Khomeini Street, before Hassan Abad Square, Sina Hospital
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Tehran
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1136746911
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Deputy Research and Technology
Street address
Keshavarz Boulevard ; Corner of Quds Street; Central Organization of Tehran University of Medical Sciences
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Province
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1417653761
Phone
+98 21 8163 3611
Email
rmo@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
sina hospital
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
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Mina naderi
Position
Internal medicine resident
Latest degree
Medical doctor
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)
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
Yes - There is 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
Title and more details about the data/document
No decision for IPD
When the data will become available and for how long
No decision for IPD
To whom data/document is available
No decision for IPD
Under which criteria data/document could be used
No decision for IPD
From where data/document is obtainable
No decision for IPD
What processes are involved for a request to access data/document
No decision for IPD
Comments