

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jun 2026

### Determining the Preventive Effect of Carvedilol on Reducing Trastuzumab 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. Carvedilol 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 Trastuzumab 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 m<sup>2</sup>, 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 University 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

##### City

Tehran

##### Province

Tehran

##### Postal code

1136746911

##### Phone

+98 21 7786 5654

##### Email

Mina.naderi89@icloud.com

## 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

##### City

Tehran

##### Province

Tehran

##### Postal code

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

Internal Medicine

##### Street address

NO 40,192 west alley, third squered of Tehranpars

##### City

Tehran

##### Province

Tehran

##### Postal code

1653858895

##### Phone

+98 21 7786 5654

##### Email

Mina.naderi89@icloud.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Mina naderi

##### Position

Resident of internal medicine

##### Latest degree

Medical doctor

##### Other areas of specialty/work

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

Tehran University of Medical Sciences

**Full name of responsible person**

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**Email**

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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**