

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of Carvedilol effect on LV function in patients treated with Herceptin due to breast cancer

Protocol summary

Summary

The aim of this study was evaluation of carvedilol effect on left ventricular function in patient who treated with herceptin and its role in prevention of herceptin induced cardiomyopathy. inclusion criteria was patient with breast cancer candidate for herceptin therapy due to positive HER 2 without attention to previous chemotherapy that have ejection fraction >50% and normal diastolic function or mild dysfunction exclusion criteria:patient who have contraindication for carvedilol .study population: 50 patient treated with herceptin for one year .25 patient will randomly receive carvedilol .All patient will evaluated by echocardiography 7 days before treatment ,3,6 ,12 months after that. primary out come is development of left ventricular dysfunction .

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015062922968N1**
Registration date: **2015-09-16, 1394/06/25**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-09-16, 1394/06/25

Registrant information

Name

Elmira Aghaei

Name of organization / entity

Hamadan Medical University

Country

Iran (Islamic Republic of)

Phone

+98 38260174

Email address

e.aghaeei@edu.umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

EKBATAN HOSPITAL

Expected recruitment start date

2015-07-23, 1394/05/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Carvedilol effect on LV function in patients treated with Herceptin due to breast cancer

Public title

Effect of Carvedilol on Heart function

Purpose

Prevention

Inclusion/Exclusion criteria

inclusion criteria: all of patient with breast cancer candidate for Herceptin therapy without attention to previous chemotherapy that have Ejection Fraction >50% and normal diastolic function or mild dysfunction exclusion criteria:patient who have contraindication for Carvedilol;grade 2or 3 AV block; Heart rate <50;systolic blood pressure<90;Asthma;chronic obstructive pulmonary disease ;liver cirrhosis;psoriasis; peripheral vascular disease

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 50

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committe of Hamedan University of Medical Sciences

Street address

Hamedan University of Medical Sciences, Pajuhesh blv, Hamedan, Iran

City

Hamedan

Postal code

۶۵۱۷۶۱۹۶۵۱

Approval date

2015-06-20, 1394/03/30

Ethics committee reference number

IR.UMSHA.REC.1394.123

Health conditions studied**1****Description of health condition studied**

Breast cancer

ICD-10 code

C50-C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes**1****Description**

Left ventricular dysfunction

Timepoint

Before chemotherapy and 3-6-12 month after that

Method of measurement

Echocardiography

Secondary outcomes

empty

Intervention groups**1****Description**

":Intervention group: " Tab Carvedilol 6/25 mg bid for 1 year

Category

Treatment - Drugs

2**Description**

Control group: Nothing

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ekbatan Hospital

Full name of responsible person

Elmira Aghaei

Street address

Ekbatan Hospital, Hamedan, Iran

City

Hamedan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice Chancellor for research of Hamedan University of Medical Sciences

Full name of responsible person

Dr Homayounfar

Street address

Ekbatan Hospital, Hamedan, Iran

City

Hamedan

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 of Hamedan 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
Ekbatan Hospital
Full name of responsible person
Elmira Aghaee
Position
Resident of Cardiology
Other areas of specialty/work
Street address
Hamedan
City
Hamedan
Postal code
Phone
+98 81 3825 1244
Fax
Email
e.agheraee@edu.umsha.ac.ir
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Ekbatan Hospital
Full name of responsible person
Elmira Aghaee
Position
Resident of Cardiology
Other areas of specialty/work
Street address
Hamedan
City
Hamedan

Postal code
Phone
+98 81 3825 1244
Fax
Email
e.agheraee@edu.umsha.ac.ir
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Ekbatan Hospital
Full name of responsible person
Elmira Aghaee
Position
Resident of Cardiology
Other areas of specialty/work
Street address
Hamedan
City
Hamedan
Postal code
Phone
+98 81 3825 1244
Fax
Email
e.agheraee@edu.umsha.ac.ir
Web page address

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