Clinical Trial Protocol
Iranian Registry of Clinical Trials

12 Jun 2026

Comparative study of captopril, spinenolactone and carvedilol on endothelial function in women with breast cancer under chemotherapy

Protocol summary

Summary

The aim of this study is to compare the effects of captopril, spironolactone and carvedilol on endothelial function in women with breast cancer who are under chemotherapy. This study is a randomized, double blind, controlled trial. The inclusion criteria includes chemotherapy candidate women with breast cancer, aged 30-70 years, having sinus rhythm and normal left ventricular ejection fraction in echocardiography. Exclusion criteria includes left ventricular ejection fraction less than 50%, previous history of myocardial infarction or known coronary artery disease, significant valvulopathy or cardiomyopathy, patients under treatment with ACEI, beta blocker, or ARB, patients currently having AF rhythm. The sampling method is easy random sampling and the number of people in each group is 32. All patients are evaluated at the time of entry for flow-mediated vasodilatation. The intervention group will then treated with captopril, spironolactone, and carvedilol for three months. These drugs are administered 48 hours prior to the first chemotherapy cycle. All patients undergo chemotherapy with the same protocol, and after three months, both patients are examined for flow-mediated vasodilatation. In addition, left ventricular ejection fraction is measured in echocardiography and diastolic function.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061034432N1**
Registration date: **2017-08-14, 1396/05/23**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-14, 1396/05/23

Registrant information

Name
Seyed Mohammad Hashemi
Name of organization / entity
Isfahan University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 31 3668 0048
Email address
mohammad_hashemi@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-chancellor of research, Isfahan University of Medical Sciences

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2019-03-20, 1397/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of captopril, spinenolactone and carvedilol on endothelial function in women with breast cancer under chemotherapy

Public title

Captopril, spironolactone and carvedilol breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Women with breast cancer

chemotherapy candidate; aged 30-70 years; having sinus rhythm; having echocardiography for LVEF (equal to or greater than 50%) Exclusion criteria: LVEF Less than 50%; previous myocardial infarction or known coronary artery disease; significant valvulopathy or cardiomyopathy (GFR <30 mm / min / 1.73m2); patients treated with ACEI, beta blocker, or ARB; drug sensitivity to ACEI, beta blocker, ARB; (SBP <90 mmHg and HR <60 beat / min); patients who currently have an AF rhythm and need treatment with class I antiarrhythmic drugs; pregnancy; dissatisfaction with participation in the research project; death

Age
From **30 years** old to **70 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Hezarjerib street, Isfahan

City
Isfahan

Postal code

Approval date
2016-10-19, 1395/07/28

Ethics committee reference number
IR.MUI.RECD.1039.3.685

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description
Mean percent of flow-mediated vasodilatation (FMD) of Brachial artery

Timepoint
Before the chemotherapy, after the chemotherapy

Method of measurement
high resolution ultrasound

2

Description
Diastolic functional index

Timepoint
Before the chemotherapy, after the chemotherapy

Method of measurement
Echocardiography

3

Description
Mean percent of left ventricular ejection fraction (LVEF)

Timepoint
Before the chemotherapy, after the chemotherapy

Method of measurement
Echocardiography

Secondary outcomes

1

Description
Blood urea nitrogen

Timepoint
Before starting the medication, two weeks after starting the medications, monthly

Method of measurement
Blood test

2

Description
creatinine

Timepoint
Before starting the medication, two weeks after starting the medications, monthly

Method of measurement
Blood test

3

Description
Sodium

Timepoint
Before starting the medication, two weeks after starting the medications, monthly
Method of measurement
Blood test

4

Description
potassium
Timepoint
Before starting the medication, two weeks after starting the medications, monthly
Method of measurement
Blood test

Intervention groups

1

Description
Intervention group: Captopril, 5.12 mg oral tablet, twice a day for three months; Spironolactone, 25 mg oral tablet, once a day for three months; Carvedilol, 125.3 mg oral tablet, twice a day for three months
Category
Treatment - Drugs

2

Description
Control group: Placebo, 5.12 mg oral tablet, twice a day for three months; Placebo, 25 mg oral tablet, once a day for three months; Placebo, 125.3 mg oral tablet, twice a day for three months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Cardiology Clinic of Chamran hospital in Isfahan
Full name of responsible person
Street address
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor of research, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Faranak Tayebi
Street address
Vice-chancellor of research, Isfahan University of Medical Sciences, Hezarjerib street, Isfahan
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor of research, Isfahan 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
Vice-chancellor of research, Isfahan University of Medical Sciences
Full name of responsible person
Dr. Faranak Tayebi
Position
Internal heart resident
Other areas of specialty/work
Street address
Hezarjerib street, Isfahan
City
Isfahan
Postal code
Phone
+98 31 3668 0048
Fax
Email
tayebifaranak@gmail.com; mohammad_hashemi@med.mui.ac.ir
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Seyed Mohammad Hashemi
Position
Interventional cardiology fellowship
Other areas of specialty/work
Street address
Hezarjerib street, Isfahan
City
Isfahan

Postal code
Phone
+98 31 3668 0048
Fax
Email
mohammad_hashemi@med.mui.ac.ir;
tayebifaranak@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Dr. Faranak Tayebi
Position
Internal heart resident
Other areas of specialty/work
Street address
Hezarjarib street, Isfahan
City
Isfahan
Postal code
Phone
+98 31 3668 0048
Fax
Email
mohammad_hashemi@med.mui.ac.ir;
tayebifaranak@gmail.com
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