

# 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

2017-08-14, 1396/05/23

#### 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

#### 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 / 1.73m<sup>2</sup>); 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

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**Phone**

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**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**

## 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*