

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of the relationship between mean heart dose in left breast cancer radiation therapy with Pro-BNP and Troponin values and left ventricular systolic function based on LVEF and GLS values in echocardiography.

Protocol summary

Study aim

Determining the relationship between mean heart dose in left breast cancer radiation therapy with Pro-BNP and Troponin values and left ventricular systolic function based on LVEF and GLS values in echocardiography

Design

Single-arm clinical trial without control group, phase 2 on 37 patients

Settings and conduct

Eligible patients are first examined in Omid Hospital and obtained informed consent and completing the disease questionnaire form, then are referred to Chamran Hospital for echocardiography. Patients will be referred to Chamran Hospital the day before starting and the last day of radiotherapy at Omid Hospital for Troponin and Pro-BNP blood tests, and 6 months later, re-echocardiography will be performed at Chamran Hospital. Finally, the results of the data regarding heart dose delivered in radiotherapy are compared with laboratory and echocardiography values to evaluate the systolic activity of the heart.

Participants/Inclusion and exclusion criteria

Inclusion criterion: patients suffering cancer in left breast. Exclusion criteria: patients under 18 years old; pregnancy; with synchronous cancer or metastasis; history of advanced heart disease or chest radiotherapy; receiving or have received trastuzumab or anthracyclines.

Intervention groups

Patients with left breast cancer undergoing radiotherapy are evaluated for cardiac systolic function before and after radiotherapy with Troponin and Pro-BNP blood tests and echocardiography in terms of heart failure.

Main outcome variables

Mean heart dose; Pro-BNP and Troponin values; Left ventricular systolic function; LVEF and GLS values.

General information

Reason for update

Acronym

Global Longitudinal Strain, Left Ventricle Ejection Fraction

IRCT registration information

IRCT registration number: **IRCT20210822052256N2**

Registration date: **2022-03-17, 1400/12/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-03-17, 1400/12/26**

Update count: **0**

Registration date

2022-03-17, 1400/12/26

Registrant information

Name

Ali Akhavan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3235 0210

Email address

aliakhavan@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-15, 1400/10/25

Expected recruitment end date

2022-05-15, 1401/02/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of the relationship between mean heart dose in left breast cancer radiation therapy with Pro-BNP and Troponin values and left ventricular systolic function based on LVEF and GLS values in echocardiography.

Public title
The effect of left breast radiotherapy on the heart.

Purpose
Diagnostic

Inclusion/Exclusion criteria
Inclusion criteria:
All patients with left breast cancer over the age of 18 that have undergone left breast radiation therapy at Omid Hospital Have not received chemotherapy or just received the TC (taxane-cyclophosphamide) chemotherapy regimen
Exclusion criteria:
Patients under 18 years old Patients with end stage or metastatic malignancy Patients with two synchronous cancers Patients with a history of heart failure with LVEF≤50% or a history of valvular heart disease or advanced congenital heart disease or proven coronary artery disease Patients with a history of chest radiation therapy Pregnant patients with breast cancer Patients receives or have received of anthracyclines and trastuzumab

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **37**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committees of School of Medicine- Isfahan University of Medical Sciences

Street address
Motahari Ave, Omid Hospital

City
Isfahan

Province
Isfahan

Postal code
8184917911

Approval date
2021-08-20, 1400/05/29

Ethics committee reference number
IR.MUI.MED.REC.1400.397

Health conditions studied

1

Description of health condition studied

Heart Failure

ICD-10 code

I50.2

ICD-10 code description

Systolic (congestive) heart failure

Primary outcomes

1

Description

Heart mean dose in radiation therapy for left breast cancer

Timepoint

Before and 6 months after left breast radiotherapy

Method of measurement

Dose volume histogram

Secondary outcomes

1

Description

Troponin

Timepoint

Before and just after left breast radiotherapy

Method of measurement

Laboratory test

2

Description

Brain natriuretic peptide

Timepoint

Before and just after left breast radiotherapy

Method of measurement

Laboratory test

3

Description

Left ventricle ejection fraction
Timepoint
Before and just after left breast radiotherapy
Method of measurement
Echocardiography

4

Description
Global longitudinal strain
Timepoint
Before and just after left breast radiotherapy
Method of measurement
Echocardiography

Intervention groups

1

Description
Intervention group: Women with left breast cancer who are treated with conventional 3D or hypofractionated radiation therapy with a dose of 50 Gy in 25 fractions or 42.5 Gy in 16 fractions.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid Hospital
Full name of responsible person
Ali Akhavan
Street address
Motahari Ave., Omid Hospital
City
Isfahan
Province
Isfahan
Postal code
8184917911
Phone
+98 31 3235 0214
Email
aliakhavan@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash
Street address
Hezar Jarib Ave., Isfahan University of Medical Science
City
Isfahan

Province
Isfahan
Postal code
8174673461
Phone
+98 31 3668 8138
Email
siavash@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
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
Esfahan University of Medical Sciences
Full name of responsible person
Ali Akhavan
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Radiation Oncology Department, Seyed-alshohada (Omid) Hospital, Motahari Ave.,
City
Isfahan
Province
Isfahan
Postal code
8184917911
Phone
+98 31 3235 0210
Fax
Email
aliakhavan@med.mui.ac.ir

Person responsible for scientific inquiries

Contact
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Person responsible for updating data

Contact

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Esfahan University of Medical Sciences

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Province

Isfahan

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Fax

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aliakhavan@med.mui.ac.ir

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

Undecided - It is not yet known if there will be 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