Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Efficacy, safety and tolerability of adding lenalidomide to neoadjuvant chemotherapy for tripple negative breast cancer

Protocol summary

Study aim
Determining the efficacy, safety, and tolerability of adding lenalidomide to neoadjuvant chemotherapy regimen in patients with triple-negative breast cancer

Design
This research project is a pilot study in the form of a randomized, single-blind trial.

Settings and conduct
Patients will undergo surgery (breast conservation or mastectomy with sentinel lymph node evaluation or axillary dissection) within 3 to 6 weeks of the last chemotherapy cycle. Response to neoadjuvant therapy will be determined based on histological evaluation of the surgical breast specimen and axillary lymph nodes.

Participants/Inclusion and exclusion criteria
According to the entry and exit criteria recorded on the previous page.

Intervention groups
Patients who are eligible to participate in the study will be enrolled in the study after a full explanation of the clinical trial process and written informed consent is obtained. The chemotherapy regimen used in this study is similar to the control group of the keynote 522 study and is 4 courses of paclitaxel 80 mg/m2 and carboplatin AUC 1.5 every week for 3 weeks (total 12 weeks) followed by 4 courses of doxorubicin 60 mg/m2 and cyclophosphamide 600 mg/m2 every 3 weeks (total 12 weeks). Patients who have entered the study will be randomly assigned to two groups in a 1:1 manner: the first group will receive the above regimen plus lenalidomide 10 mg for 2 weeks on and 1 week off. Patients will also receive aspirin for VTE prophylaxis. The second group will receive the above regimen plus a placebo in a similar manner to lenalidomide. Before randomization, patients will be classified based on lymph node involvement (positive or negative) and tumor size (T1/T2 vs. T3/T4).

Main outcome variables
This information will help clinicians use effective, less-complicated, and less-costly treatment methods in neoadjuvant chemotherapy for triple-negative breast cancer.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250927067373N1**
Registration date: **2025-10-20, 1404/07/28**
Registration timing: **registered_while_recruiting**

Last update: **2025-10-20, 1404/07/28**
Update count: **0**

Registration date
2025-10-20, 1404/07/28

Registrant information

Name
sara razdar

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 920 071 5864

Email address
drsrazdar@gmail.com

Recruitment status
recruiting

Funding source

Expected recruitment start date
2025-10-11, 1404/07/19

Expected recruitment end date
2026-10-22, 1405/07/30

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy, safety and tolerability of adding lenalidomide to neoadjuvant chemotherapy for tripple negative breast cancer

Public title

Efficacy, safety and tolerability of adding lenalidomide to neoadjuvant chemotherapy for tripple negative breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

1- Written consent to participate in the study 2- Female over 18 years of age at the time of study entry 3- Triple-negative breast cancer based on the pathology report of the biopsy of the breast mass 4- Absence of metastasis in radiological evaluations 5- Not receiving immunotherapy 6- Primary tumor status T1c-T4d 7- Lymph node involvement N0-N2 ECOG 0-1 9- Proper functioning of internal organs 10- LVEF greater than 50% on echocardiography 11- Negative HCG test within 72 hours before the start of pregnancy and consent to use contraceptive methods for up to 1 year after the end of chemotherapy.

Exclusion criteria:

1- History of cancer in the past 5 years except basal or squamous cell skin cancer or cervical cancer in situ 2- Receiving chemotherapy, radiotherapy or immunotherapy in the past 1 year 3- Active infection requiring systemic treatment 4- HIV, hepatitis B, hepatitis C or active TB 5- Serious cardiovascular disease such as myocardial infarction or angioplasty in the past 6 months or CHF NYHA class II-IV 6- History of DVT or PTE 7- Known thrombophilia 8- Psychiatric illness or substance abuse that interferes with patient compliance with treatment 9- Pregnancy or breastfeeding 10- Receiving immunotherapy

Age

From **18 years** old

Gender

Female

Phase

2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization is done one by one.

Blinding (investigator's opinion)

Single blinded

Blinding description

The evaluating pathologist is unaware of the grouping and type of intervention.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of tehran University of Medical Sciences

Street address

Imam Khomeini Hospital Complex, end of Keshavarz Boulevard

City

tehran

Province

Tehran

Postal code

1419733141

Approval date

2024-12-22, 1403/10/02

Ethics committee reference number

IR.TUMS.IKHC.REC.1403.396

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Disease Grade on Pathological Response to Neoadjuvant Chemotherapy Diet Containing Lenlidomide and Placebo in Surgical Sample

Timepoint

after surgery

Method of measurement

patologic assessment

Secondary outcomes

empty

Intervention groups

1

Description

Patients who are eligible to participate in the study will be enrolled in the study after a full explanation of the clinical trial process and written informed consent is obtained. The chemotherapy regimen used in this study is similar to the control group of the keynote 522 study and is 4 courses of paclitaxel 80 mg/m2 and carboplatin AUC 1.5 every week for 3 weeks (total 12 weeks) followed by 4 courses of doxorubicin 60 mg/m2 and cyclophosphamide 600 mg/m2 every 3 weeks (total 12 weeks). Patients who have entered the study will be randomly assigned to two groups in a 1:1 manner: the first group will receive the above regimen plus lenalidomide 10 mg for 2 weeks on and 1 week off. Patients will also receive aspirin for VTE prophylaxis. The second group will receive the above regimen plus a placebo in a similar manner to lenalidomide. Before randomization, patients will be classified based on lymph node involvement (positive or negative) and tumor size (T1/T2 vs. T3/T4). During the study, a physician will be responsible for recording all adverse events that occurred for patients according to the CTCAE version 5 guidelines. Changes in drug doses, drug discontinuations, or delays in chemotherapy courses based on adverse events will all be recorded.Patients will undergo surgery (breast conservation or mastectomy with sentinel lymph node evaluation or axillary dissection) within 3 to 6 weeks of the last chemotherapy cycle. Response to neoadjuvant therapy will be determined based on histological evaluation of the surgical breast specimen and axillary lymph nodes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran - Imam Khomeini Hospital
Full name of responsible person
Razdar sara
Street address
Tohid Square - Imam Khomeini Hospital
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tehran 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
Tehran University of Medical Sciences
Full name of responsible person
Razdar sara
Position
Specialist Assistant
Latest degree
Subspecialist
Other areas of specialty/work
hemato-oncology
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Person responsible for scientific inquiries

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Position
Specialist Assistant

Latest degree
Subspecialist

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
article

When the data will become available and for how long
one year

To whom data/document is available
no one

Under which criteria data/document could be used
article

From where data/document is obtainable
drsrazdar@gmail.com

What processes are involved for a request to access data/document
drsrazdar@gmail.com

Comments