

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

City

Tehran

Province

Tehran

Postal code

1419733141

Phone

+98 912 071 5864

Email

drsrazdar@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

razdar sara

Street address

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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

Street address

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City

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Phone

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Email

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Person responsible for scientific 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

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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Position

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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