# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Oct 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**
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**Postal code**
1419733141
**Phone**
+98 912 071 5864
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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**
Tohid Square - Imam Khomeini Hospital
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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
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**Full name of responsible person**
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**Position**
Specialist Assistant

**Latest degree**
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**Other areas of specialty/work**
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## Person responsible for updating data

**Contact**

**Name of organization / entity**
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**Position**
Specialist Assistant

**Latest degree**
Subspecialist

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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**