Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the therapeutic effect of aspirin in combination with standard chemotherapy regimens compared to placebo in breast cancer

Protocol summary

Study aim

Investigation of the effect of aspirin on pathological response of neoadjuvant chemotherapy in breast cancer patients referred to Kerman Afzalipur Hospital in 2024-2025

Design

The current study will be a triple-blinded randomized clinical trial that will be conducted in Afzalipur Hospital, Kerman, during the years 2024 and 2025. The target population of this study will be women with breast cancer referred to the radio-oncology department of Afzalipur Hospital.

Settings and conduct

This study will follow a triple blind design. In this way, neither the participants, nor the researchers involved in data collection, nor the statistical analyst of the project will be aware of the group to which the patients have been assigned. The location of this study is Afzalipur Hospital.

Participants/Inclusion and exclusion criteria

1. Women aged 18 to 70 with breast cancer who have been confirmed by histopathological diagnosis 2. Stage II to III who are candidates for neoadjuvant chemotherapy 3. Zero or one ECOG performance index 4. Informed consent to enter the study

Intervention groups

In this study, all patients will receive standard neoadjuvant chemotherapy regimens based on the hemato-oncology specialist's prescription. Chemotherapy regimens will include regimens based on cyclophosphamide, adriamycin, and taxols. Participants who meet the inclusion and exclusion criteria of the study will be randomly assigned 1:1 to receive aspirin or placebo during their neoadjuvant chemotherapy treatment.

Main outcome variables

Primary outcome pathological complete response Secondary outcome side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241015063367N1**
Registration date: **2024-12-16, 1403/09/26**
Registration timing: **registered_while_recruiting**

Last update: **2024-12-16, 1403/09/26**
Update count: **0**

Registration date

2024-12-16, 1403/09/26

Registrant information

Name

Roghaye Abdollahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3325 7236

Email address

roghayeabdollahi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-10-22, 1403/08/01

Expected recruitment end date

2025-04-20, 1404/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of aspirin in combination with standard chemotherapy regimens compared to placebo in breast cancer

Public title
Investigating the effect of aspirin in breast cancer
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
1. Women aged 18 to 70 with breast cancer who have been confirmed by histopathological diagnosis 2. Stage II to III who are candidates for neoadjuvant chemotherapy 3. Zero or on Eastern Cooperative Oncology Groupperformance index 4. Informed consent to enter the study
Exclusion criteria:
1. Patients with a history of other malignancies, a history of myocardial infarction, a history of atrial fibrillation, and a history of grade hypertension 2. Contraindications of aspirin use 3. Simultaneous use of warfarin, heparin or heparin analogues, clopidogrel, thrombin inhibitors or coagulation factors 4. History of taking aspirin within 30 days before entering the study
Age
From **18 years** old to **70 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, all patients will receive standard neoadjuvant chemotherapy regimens based on the prescription of a hemato-oncology specialist. Chemotherapy regimens will include regimens based on cyclophosphamide, adriamycin, and taxols. Participants who meet the inclusion and exclusion criteria of the study will be randomly assigned 1:1 to receive aspirin or placebo during their neoadjuvant chemotherapy treatment after obtaining informed consent and explaining the research objectives. Randomization will be performed using a computerized randomization sequence. Patients in the intervention group will be treated with aspirin 100 mg daily during the period of neoadjuvant chemotherapy. Patients in the control group are similarly receiving placebo daily during the period of neoadjuvant chemotherapy. The placebo will be delivered to the patients in the control group in capsules with the same appearance as aspirin but without the effective pharmacological substance. The distribution of patients in the two groups is similar in terms of disease stage and hormone receptor
Blinding (investigator's opinion)
Triple blinded
Blinding description
This study will follow a triple blind design. In this way, neither the participants, nor the researchers involved in data collection, nor the statistical analyst of the project will be aware of the group to which the patients have been assigned. Aspirin and placebo capsules will look identical. A third party not involved in the measurement of outcomes and analysis of results will be responsible for labeling the study drugs according to the randomized sequence and maintaining the blinding process of the study until the end of the data analysis. Unblinding will only be done if a medical emergency occurs during the study for the patient that requires knowledge of the prescribed treatment, in which case the patient will be excluded from the study.
Placebo
Used
Assignment
Factorial
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of kerman University of Medical Sciences
Street address
Emam khomeini
City
Kerman
Province
Kerman
Postal code
۷۶۱۶۹۱۳۳۵۵
Approval date
2024-09-23, 1403/07/02
Ethics committee reference number
IR.KMU.AH.REC.1403.109

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

Complete pathologic response

Timepoint

4 month

Method of measurement

Pathology report

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: after obtaining informed consent and explaining the objectives of the research, aspirin 81 milligrams daily is given to the intervention group

Category

Treatment - Other

2

Description

Control group: A placebo is given to the control group

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipur hospital

Full name of responsible person

Maryam Bahador

Street address

Emam Khomeini

City

Kerman

Province

Kerman

Postal code

۷۶۱۶۹۱۳۳۵۵

Phone

+98 34 3132 8000

Email

roghayeabdollahi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Saeed Ahmadzade

Street address

Imam Highway, Afzalipur Hospital

City

Kerman

Province

Kerman

Postal code

۷۶۱۶۹۱۳۳۵۵

Phone

+98 34 3132 8000

Email

roghayeabdollahi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Roghaye Abdollahi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

Street address

Imam Highway, Afzalipur Hospital

City

Kerman

Province

Kerman

Postal code

۷۶۱۶۹۱۳۳۵۵

Phone

+98 34 3132 8000

Email

roghayeabdollahi@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Maryam Bahador

Position
Professor
Latest degree
Specialist
Other areas of specialty/work
Radiotherapy
Street address
Emam Khomeini
City
Kerman
Province
Kerman
Postal code
۷۶۱۶۹۱۳۳۵۵
Phone
+98 34 3132 8000
Email
maryamb2003@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Kerman University of Medical Sciences
Full name of responsible person
Roghaye Abdollahi
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Radiotherapy
Street address
Emam Khomeini
City
Kerman
Province
Kerman
Postal code
۷۶۱۶۹۱۳۳۵۵
Phone
+98 34 3132 8000
Email
roghayeabdollahi@yahoo.com

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
On website
When the data will become available and for how long
After publishing
To whom data/document is available
Every one
Under which criteria data/document could be used
For searching, treatment
From where data/document is obtainable
Internet Email roghayeabdollahi@yahoo.com
What processes are involved for a request to access data/document
After searching on internet it is accessible
Comments