Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of letrozole and neoadjuvant cheotherapy with chemotherapy alone on clinical response in advanced hormonal breast cancer

Protocol summary

Study aim

Effect of letrozole in combination with neoadjuvant chemotherapy on positive hormone breast cancer.

Design

In this randomized controlled trial, a randomized, control group of 48 women with invasive breast cancer in the IIA to IIIC (T1-4, N0-3, M0), hormone receptor positive and negative HER2, Will be selected. Patients are randomly selected and divided into intervention and control groups. In the intervention group, hormone therapy added to chemotherapy, and control group given only chemotherapy. After completion of treatment, the clinical response, size of the breast and axillary lymph nodes, are evaluated by touch and then calipers.
Ultrasonography is also repeated, and the patient is referred for surgery. The pathologic response rate is also assessed on post-surgical specimens.

Settings and conduct

Before the treatment, the complete physical examination is performed, the size of the breast mass and the axillary lymph nodes is measured using calipers and ultrasound. Chemotherapy with hormone therapy in the intervention group and chemotherapy alone in the control group according to The standard protocol starts. At the end of each cycle, breast and axillary is examined and the possible side effects of the treatment are evaluated. At the end of the chemotherapy, a clinical evaluation is performed with physical exam and ultrasonography, and after surgery pathologic response is evaluate. The location of the study is a university-affiliated medical center and private office.

Participants/Inclusion and exclusion criteria

Entry criteria: Patients with advanced advanced hormone breast cancer, aged> 18 years, lack of chemotherapy
Exit criteria: Pregnancy Lactation, history of thromboembolic events in the patient, history of osteoporotic fractures

Intervention groups

Letrozole and chemotherapy in patients group, control group only receives chemotherapy.

Main outcome variables

The response rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042091N1**
Registration date: **2019-02-27, 1397/12/08**
Registration timing: **prospective**

Last update: **2019-02-27, 1397/12/08**
Update count: **0**

Registration date

2019-02-27, 1397/12/08

Registrant information

Name

Zahra Mozaheb

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3833 2711

Email address

mozahebz@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-03-01, 1397/12/10

Expected recruitment end date

2020-10-31, 1399/08/10

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of letrozole and neoadjuvant cheotherapy with chemotherapy alone on clinical response in advanced hormonal breast cancer

Public title
Evaluation of the effect of hormone therapy in breast cancer before surgery
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
female with invasive breast cancer with positive hormone receptor and negative HER2 proven in pathology Clinical Phase IIA to IIIC (T1-4, N0-3, M0) Age more than 18 years Good performance ((ECOG: 0-1 No history of previous chemotherapy It is a conscientious informed consent
Exclusion criteria:
Pregnancy / Breastfeeding Liver cirrhosis History of thromboembolic events in the patient History of osteoporotic fractures Patient's lack of cooperation in correct implementation of the treatment process in accordance with the recommended guidelines
Age
From **18 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **48**
Actual sample size reached: **48**
Randomization (investigator's opinion)
Randomized
Randomization description
simple randomization
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics commitee of Mashhad University of Medical Sciences
Street address
Daneshgah st, ghorashi building,Research and Technology Deputy
City
Mashhad
Province
Razavi Khorasan
Postal code
9138813944
Approval date
2018-12-11, 1397/09/20
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.457

Health conditions studied

1

Description of health condition studied
Breast cancer
ICD-10 code
C50
ICD-10 code description
Malignant neoplasm of breast, endocrine therapy, neoadjuvant

Primary outcomes

1

Description
Clinical response rate
Timepoint
Clinical examination before and after treatment of Neo-adjuvant
Method of measurement
clinical examination and Sonography

Secondary outcomes

1

Description
pathologic response
Timepoint
after surgery
Method of measurement
pathologic response rate

Intervention groups

1

Description
Intervention group: Neoadjuvant patients treated with doxorubicin chemotherapy (60mg / m2) and

cyclophosphamide (2600mg / m 2) every 2 weeks for 4 cycles, followed by paclitaxol (175mg / m 2) every 2 weeks for 4 cycles, and letrozole 1 per day , Patient with pre-menopausal zoladex 3.6 mg every 28 days of subcutaneous administration 2 weeks before treatment.

Category
Treatment - Drugs

2

Description
Control group: Only chemotherapy is given.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam-Raza hospital

Full name of responsible person
Zahra Mozaheb

Street address
Imam Reza hospital,Imam Reza square،Ebnesina St,

City
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Mozahebz@mums.ac.ir

Web page address
http://www.mums.ac.ir/

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Mohsen Tafaghodi phd

Street address
Deputy of Research and Technology of the Mashhad University of Medical Science, opposite University of Ave. 18, Daneshgah Street

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+98 51 3841 2081

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vcresearch@mums.ac.ir

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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
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Zahra Mozaheb

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Hematology

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Hematology- Oncology department,Imam Reza hospital، Imam reza square,

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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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
General information of patients and the main outcome and analyzed data

When the data will become available and for how long
After completing sample size

To whom data/document is available
People working at university centers

Under which criteria data/document could be used
In the case of access, they do not have any analysis and interpretation before the article is published

From where data/document is obtainable
Email:mozahebz@mums.ac.ir

What processes are involved for a request to access data/document
After requesting and reasoning, the need for this information and how to use this information are available within 1 week, if available.

Comments