

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of letrozole and neoadjuvant chemotherapy 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 committee 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 / m²) every 2 weeks for 4 cycles, followed by paclitaxol (175mg / m²) 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,

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Email

Mozahebz@mums.ac.ir

Web page address

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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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Web page address**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**Contact****Name of organization / entity**

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Full name of responsible person

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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