

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of Ki67 factor changes after 7 days treatment with Letrozol in postmenopausal women with an early stage breast cancer and hormone receptor positive

Protocol summary

Study aim

Evaluation of changes the cell proliferation factor (ki67%) before and after 7 days treatment with Letrozol in early stage breast cancer with hormone positive receptor

Design

This study will perform in one group (n = 40) with before-after evaluation. Randomization and blinding is not applicable in this study.

Settings and conduct

In university hospitals (Cancer Institute of Imam Khomeini Hospital, Arash Women's Hospital), patients should be on the waiting list for at least one week. In this study, one Letrozol tablet (2.5 mg/day) for 7 days before surgery will administer to patients. Ki67%factor is routinely measured in all patients undergoing core biopsy (before intervention) and after drug administration and surgery, the ki67% factor will be measured again by a pathologist. Ki67 levels will be measured at Imam Khomeini Hospital. Meanwhile, Letrozol will have long-term side effects such as hot flashes and vaginal bleeding, which logically will not occur with a one-week dose.

Participants/Inclusion and exclusion criteria

Inclusion criteria 1. Breast cancer patients 2. Early stage of disease 3. Postmenopausal women 4. Hormone receptor positive Exclusion criteria 1. Metastatic breast cancer 2. Other sub-types of breast cancer 3. Pre-menopausal women

Intervention groups

This study will perform in one group which evaluates before-after treatment. In patients who wait for the time of surgery, for 7 days Letrozol tablet will be prescribed (2.5 mg/day) and cell proliferation factor (ki67%) before and after treatment will measure.

Main outcome variables

Cell proliferation factor (ki67%) level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101104005101N2**

Registration date: **2022-05-10, 1401/02/20**

Registration timing: **retrospective**

Last update: **2022-05-10, 1401/02/20**

Update count: **0**

Registration date

2022-05-10, 1401/02/20

Registrant information

Name

ramesh omranipour

Name of organization / entity

tehran university of medical science

Country

Iran (Islamic Republic of)

Phone

+98 21 6658 1571

Email address

omranipour@sina.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-25, 1398/12/06

Expected recruitment end date

2021-02-24, 1399/12/06

Actual recruitment start date

2020-02-25, 1398/12/06

Actual recruitment end date

2022-02-25, 1400/12/06

Trial completion date

2022-02-25, 1400/12/06

Scientific title

Evaluation of Ki67 factor changes after 7 days treatment with Letrozol in postmenopausal women with an early stage breast cancer and hormone receptor positive

Public title

Effect of Letrozol in cell proliferation marker of breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Breast cancer patients Early stage of disease With hormone receptor positive Postmenopausal women

Exclusion criteria:

Metastatic breast cancer Premenopausal women Other sub-types of breast cancer

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Actual sample size reached: **25**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Before-after treatment in a single group

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran University of Medical Sciences

Street address

TUMS building, Ghods Avenue., Keshavarz Boulevard,

City

Tehran

Province

Tehran

Postal code

1419733141

Approval date

2020-02-18, 1398/11/29

Ethics committee reference number

IR.TUMS.VCR.REC.1398.966

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

Cell proliferation factor (Ki67)

Timepoint

Measurement of ki67% level at the beginning of the study (before intervention) and one week after using Letrozol tablet

Method of measurement

Ki-67 will be calculated using scoring systems to estimate a proliferation index (PI); the number of positively stained tumor nuclei divided by the total number of nuclei in a specific region by pathologists.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Prescription of Letrozol tablet (IRAN HORMONE PHARMACEUTICAL CO.) 2.5 mg/day for 1 week before surgery and comparison of Ki67% level before and after drug consumption.

Category

Treatment - Drugs

2

Description

Control group: Not applicable in this study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Institute of Imam Khomeini Hospital
Full name of responsible person
Ramesh Omranipour
Street address
Keshavarz Blvd., Imam Khomeini Hospital
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2

Recruitment center

Name of recruitment center
Arash Women's Hospital
Full name of responsible person
Sadaf Alipour
Street address
162 Ave., Shahid Baghdarnia Street, Resalat Highway
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Postal code
1653915981
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sadafalipour@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Ramesh Omranipour
Street address
Breast Disease Research Center, Sadaf building,
Imam Khomeini hospital, Keshavarz Blvd., Tehran,
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omranipour@tums.ac.ir
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
Ramesh Omranipour
Position
Professor
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
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Person responsible for scientific inquiries

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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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Scientific paper

When the data will become available and for how long

Starting access after printing paper

To whom data/document is available

For everyone

Under which criteria data/document could be used

Access to the basic data will be granted with the consent of the university.

From where data/document is obtainable

Dr. Ramesh Omranipour

What processes are involved for a request to access data/document

Basic data and published article will be available through request by email from Dr. Omranipour after the permission from the university.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Bitā Eslami

Position

Assistant professor

Latest degree

Ph.D.

Other areas of specialty/work

Reproductive Biology

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