

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jun 2026

Investigating and Comparing the Association of Fatty Liver with Tamoxifen and Letrozole in Premenopausal Patients with Breast Cancer

Protocol summary

Study aim

Evaluation and comparison of fatty liver with Tamoxifen and Letrozole in premenopausal breast cancer patients

Design

Progesterone receptor or Estrogen receptor positive patients who meet the conditions to enter the study are included in the study by continuous sampling method. They are treated with chemotherapy. They are divided into two groups by random allocation method. The first group of breast cancer patients are treated with tamoxifen and the second group with Letrozole. In both groups, in two stages, once after the completion of chemotherapy and the second time at least 6 months after taking tamoxifen and Letrozole drugs, abdominal ultrasound is performed to evaluate fatty liver.

Settings and conduct

In both groups of menopausal patients with Brest cancer referred to Qazvin Velayat Hospital and private practice (under treatment with tamoxifen and letrozole) in two stages, once after completion of chemotherapy and the second time at least 6 months after taking tamoxifen and letrozole drugs. Abdominal examination is done to evaluate fatty liver.

Participants/Inclusion and exclusion criteria

The criteria for entering the study include premenopausal breast cancer patients (PR or ER positive) and the exclusion criteria include having any risk factor for fatty liver or underlying liver problems (abdominal ultrasound is used to check for fatty liver) If there is evidence in favor of fatty liver, they are excluded from the study.)

Intervention groups

The first group of Brest cancer patients are treated with tamoxifen and the second group with letrozole

Main outcome variables

Alanine transaminase Aspartate Transaminase Severity of fatty liver

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221126056616N1**

Registration date: **2022-12-08, 1401/09/17**

Registration timing: **prospective**

Last update: **2022-12-08, 1401/09/17**

Update count: **0**

Registration date

2022-12-08, 1401/09/17

Registrant information

Name

Mohammad Nazarinia

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3377 3721

Email address

m.nazarinia99@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-12-22, 1401/10/01

Expected recruitment end date

2023-12-22, 1402/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating and Comparing the Association of Fatty Liver with Tamoxifen and Letrozole in Premenopausal Patients with Breast Cancer

Public title

Investigating and Comparing the Association of Fatty Liver with Tamoxifen and Letrozole in Premenopausal Patients with Breast Cancer

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Premenopausal breast cancer patients (Progesterone receptor or Estrogen receptor positive).

Exclusion criteria:

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Progesterone receptor or Estrogen receptor positive patients who meet the conditions to enter the study are included in the study by continuous sampling method. They are treated with chemotherapy. They are divided into two groups by random allocation method. The first group of breast cancer patients are treated with Tamoxifen and the second group with Letrozole.

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 qazvin University of Medical Sciences

Street address

Research and Technology deputy ,Mavaddat Alley,Shahid Beheshti Blvd,Qazvin

City

Qazvin

Province

Qazvin

Postal code

3413996134

Approval date

2022-11-23, 1401/09/02

Ethics committee reference number

IR.QUMS.REC.1401.246

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

2

Description of health condition studied

Fatty Liver

ICD-10 code

K76.0

ICD-10 code description

Fatty (change of) liver, not elsewhere classified

Primary outcomes

1

Description

Severity of fatty liver

Timepoint

6 months after taking tamoxifen and letrozole drugs

Method of measurement

Ultrasound

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Patients with Brest cancer treated with Letrozole

Category

Treatment - Drugs

2

Description

Control group: Patients with Brest cancer treated with Tamoxifen

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Velayat hospital

Full name of responsible person

Mohammad Nazarinia

Street address

22 Bahman Blvd., Minoodar region

City

Qazvin

Province

Qazvin

Postal code

3471976161

Phone

+98 28 3379 0620

Email

m.nazarinia99@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Nazarinia

Street address

Bahonar street

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3333 6001

Email

medicine@qums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Nazarinia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Bahonar street

City

Qazvin

Province

Qazvin

Postal code

34197-58911

Phone

+98 28 3333 6001

Email

m.nazarinia99@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Nazarinia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Bahonar street

City

Qazvin

Province

Qazvin

Postal code

34197-58911

Phone

+98 28 3333 6001

Email

m.nazarinia99@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Mohammad Nazarinia

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

Street address

Bahonar street

City

Qazvin

Province

Qazvin

Postal code

34197-58911

Phone

+98 28 3333 6001

Email

m.nazarinia99@gmail.com

Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available