

# 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**

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## Person responsible for scientific inquiries

### Contact

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Mohammad Nazarinia

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Internal Medicine

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## 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**

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**Email**

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**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