

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Determination of efficacy and safety of adding Oxaliplatin to neoadjuvant chemotherapy in locally advanced breast cancer patients

Protocol summary

Study aim

Determination of percentage of pathologic complete response by adding Oxaliplatin to neoadjuvant chemotherapy regimen in locally advanced breast cancer; Determination of drug toxicity(including hematologic,hepatic, renal toxicity) by adding Oxaliplatin to neoadjuvant chemotherapy regimen in locally advanced breast cancer

Design

Non randomized and non controlled phase 2 single arm clinical trial

Settings and conduct

locally advanced breast cancer patient who will be treated in radiation oncology department of Shiraz Namazi hospital will be treated by 4 courses doxorubicin and cyclophosphamide then 4 course docetaxel and oxaliplatin every 3 weeks and evaluated in terms of pathologic complete response and drug toxicity.

Participants/Inclusion and exclusion criteria

Female adults (20-70 years old) who are histopathologically confirmed locally advanced breast cancer (clinical stage T3, T4, and/or N2, N3) with Eastern Cooperative Oncology Group Performance status of 0 or 1 and acceptable complete blood count, liver function test, renal function test; The patient should not have active infection, pregnancy, other primary malignancy, any documented distant metastasis, uncontrolled systemic diseases. (including severe cardiovascular, kidney and liver disease) and refusal to participate in this trial.

Intervention groups

Adding oxaliplatin to neoadjuvant chemotherapy regimen

Main outcome variables

pathologic response

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181224042104N1**

Registration date: **2019-03-28, 1398/01/08**

Registration timing: **prospective**

Last update: **2019-03-28, 1398/01/08**

Update count: **0**

Registration date

2019-03-28, 1398/01/08

Registrant information

Name

Mehdi Shariat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3636 3183

Email address

mshariat@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-06, 1398/01/17

Expected recruitment end date

2019-06-21, 1398/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Determination of efficacy and safety of adding Oxaliplatin to neoadjuvant chemotherapy in locally advanced breast cancer patients

Public title

Determination of efficacy and safety of Oxaliplatin in locally advanced breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Histologically confirmed locally advanced breast cancer
Clinical stage T3, T4, and/or N2, N3 Patients with Eastern Cooperative Oncology Group performance status of 0 or 1
Absolute neutrophil count > 1500/mm³ Hemoglobin > 8.0 g/dL Platelet count > 100,000/mm³ Creatinine < 2.5 times the upper limit of normal (ULN) Serum transaminases < 2.5 times ULN Serum alkaline phosphatase < 4 times ULN Total bilirubin < 2.5 times ULN

Exclusion criteria:

Active infection Pregnancy Other primary malignancy
Any documented distant metastasis Uncontrolled systemic diseases (including severe cardiovascular, kidney and liver disease) Patients refusal to participate in the trial

Age

From **20 years** old to **70 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor for Research, Shiraz faculty of Medicine, Zand Ave, Shiaz faculty of Medicine, Zand Ave

City

Shiraz

Province

Fars

Postal code

7134845794

Approval date

2018-01-16, 1396/10/26

Ethics committee reference number

IR.SUMS.MED.REC.1396.80

Health conditions studied**1****Description of health condition studied**

locally advanced breast cancer

ICD-10 code

C50.919

ICD-10 code description

Malignant neoplasm of unspecified site of unspecified female breast

Primary outcomes**1****Description**

Percentage of pathologic complete response

Timepoint

After surgery

Method of measurement

Histopathologic evaluation

Secondary outcomes**1****Description**

drug toxicity including hematologic,hepatic renal toxicity

Timepoint

every 3 weeks during patients visit

Method of measurement

blood test for evaluation of hematologic; renal; hepatic factors

Intervention groups**1****Description**

Intervention group: adding oxaliplatin with dose 130 mg per m² for 4 cycles every 3 weeks to chemotherapy regimen

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center

Namazi hospital

Full name of responsible person

Mehdi Shariat

Street address

Namazi Hospital; Namzi Square; Shiraz

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7193711351

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Email

radiodept4@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Seyed Basir Hashemi

Street address

Vice-Chancellor for Research; Shiraz University of Medical Sciences; Zand Blvd; Shiraz

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Shiraz

Province

Fars

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+98 71 3235 7282

Fax

+98 71 3230 7594

Email

vcrdep@sums.ac.ir

Web page address

<http://research.sums.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Mansoor Ansari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Radiotherapy

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Radiation oncology department; Namazi hospital; Namazi square

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mehdi Shariat

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Radiotherapy

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Fax**Email**

mshariat@sums.ac.ir

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

All data after becoming unidentifiable can be shared

When the data will become available and for how long

One year after publishing results

To whom data/document is available

Data will only be available to academic researchers

Under which criteria data/document could be used

Any use of data is subject to the condition of mentioning the source

From where data/document is obtainable

Mahdi Shariat Namazi Hospital; Namazi Square; Shiraz
Through E-mail : mshariat@sums.ac.ir

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

About one week after sending request to email,
requested data will be sent

Comments