

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of clinical, radiologic and pathologic response rates of neoadjuvant chemotherapy regimen containing doxorubicin and cyclophosphamide with paclitaxel and gemcitabine in locally advanced breast cancer

#### Protocol summary

##### Summary

(1) Objectives: Comparison of clinical, radiological and pathological response rates of neoadjuvant chemotherapy regimen containing doxorubicin and cyclophosphamide (AC) with paclitaxel and gemcitabine (PG) in locally advanced breast cancer. 1) Determination of clinical tumor and lymph nodes response to neoadjuvant chemotherapy with doxorubicin and cyclophosphamide based on comparison of the sizes of them before and after chemotherapy 2) Determination of clinical tumor and lymph nodes response to neoadjuvant chemotherapy with paclitaxel and gemcitabine based on comparison of the sizes of them before and after chemotherapy. 3) Determination of radiological tumor and lymph nodes response to neoadjuvant chemotherapy with doxorubicin and cyclophosphamide based on comparison of the sizes of them before and after chemotherapy by sonography. 4) Determination of radiological tumor and lymph nodes response to neoadjuvant chemotherapy with paclitaxel and gemcitabine based on comparison of the sizes of them before and after chemotherapy by sonography. 5) Determination of pathological tumor and lymph nodes response to neoadjuvant chemotherapy based on specimen of residual tumor after chemotherapy between 2 groups. 6) Determination of clinical tumor and lymph nodes response to neoadjuvant chemotherapy between 2 groups based on physical exam. 7) Determination of radiological tumor and lymph nodes response to neoadjuvant chemotherapy between 2 groups by sonography. 8) Prevalence of side effect (extremity edema, bone marrow suppression, alopecia) of neoadjuvant chemotherapy regimen. (2) Design: Patients with locally advanced breast cancer were randomly assigned into 2 categories. Group 1 received AC (doxorubicin and cyclophosphamide) and the other group

received GP (paclitaxel and gemcitabine). Primary tumor size by clinical and radiological evaluation were done and registered according different characteristics such as ulceration, peau d orange sign, having skin or chest wall fixation or not, palpable and matted axillary and supraclavicular lymph nodes. Patients received 4 cycles of chemotherapy regimen every 3 week and after receiving each chemotherapy cycle, changes of size and characteristics of clinical tumor is evaluated and each patients should performed cell blood count and liver function test, renal function test, sodium and potassium test. Finally before referring the patients for surgery, the size of tumor is evaluated clinically and by breast sonography one more time and also after surgery the size of tumor is evaluated in pathological specimen. According to RECIST criterion in pathology specimen after surgery, if there was disappearance of tumor, it means the response to the treatment was completed; and if 30% decrease in sum of longest diameters the response was partial. Progression was achieved when 20% increase in sum of longest diameter or appearance of new lesions. If no progression or partial response, stable disease was diagnosed. (3) Setting and conduct: according to statistic study, 70 patients with breast cancer pathology at stages IIB or III based on AJCC10 randomized in 2 groups (each group with 35 patients) according to WWW.RANDOM.ORG. They were referred to radiation department of Namazi hospital in 2014 and participate in this trial. (4) Participants including major eligibility criteria: A) Inclusion criteria: positive pathology of breast cancer; Karnofsky performance status at least: 70; locally advanced breast cancer; age < 65 Years old; normal cardiac and liver and bone marrow function; normal and acceptable cardiac evaluation in high risk patients or past medical history of cardiac problem; filling the informed consent by patient. B) Exclusion criteria: Receiving previous chemotherapy for breast cancer; clinical or pathological positive evidence of

metastasis; underlying disease which can't receive chemotherapy; known contraindication for chemotherapy agent (taxan reaction); severe cardiac problem history such as heart failure, chest pain which needs medication, severe cardiac valve disease, myocardial infarction, uncontrolled blood pressure (systolic pressure above 180 mm/Hg and diastolic pressure above 100 mm/Hg); refusing treatment by patient. (5) Intervention: according to randomized group, one group received doxorubicin 60 mg/m<sup>2</sup> and Cyclophosphamide 600 mg/m<sup>2</sup> on the first day and in the other arm Gemcitabine 1000 mg/m<sup>2</sup>, days 1 and 8, Paclitaxel 175 mg/m<sup>2</sup> day 1 were used. Both regimens were repeated every 3 weeks. (6) Main outcome measures (variables): physical exam before starting treatment and after each cycle of chemotherapy; Sonography before starting treatment and after completeness of chemotherapy; pathological response after chemotherapy.

## General information

### Acronym

### IRCT registration information

IRCT registration number: **IRCT2014051117644N1**

Registration date: **2015-06-15, 1394/03/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

### Registration date

2015-06-15, 1394/03/25

### Registrant information

#### Name

Leila Moadabshoar

#### Name of organization / entity

Shiraz University of Medical Science

#### Country

Iran (Islamic Republic of)

#### Phone

+98 71 3612 5337

#### Email address

moadabshoar@sums.ac.ir

### Recruitment status

**Recruitment complete**

### Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

### Expected recruitment start date

2014-05-17, 1393/02/27

### Expected recruitment end date

2015-02-20, 1393/12/01

### Actual recruitment start date

empty

### Actual recruitment end date

empty

### Trial completion date

empty

### Scientific title

Comparison of clinical, radiologic and pathologic response rates of neoadjuvant chemotherapy regimen containing doxorubicin and cyclophosphamide with paclitaxel and gemcitabine in locally advanced breast cancer

### Public title

Comparison of 2 type of neoadjuvant chemotherapy in breast cancer

### Purpose

Treatment

### Inclusion/Exclusion criteria

A) Inclusion criteria: positive pathology of breast cancer; Karnofsky performance status at least: 70; locally advanced breast cancer; age < 65 Years old; normal cardiac and liver and bone marrow function; normal and acceptable cardiac evaluation in high risk patients or past medical history of cardiac problem; filling the informed consent by patient. B) Exclusion criteria: receiving previous chemotherapy for breast cancer; clinical or pathological positive evidence of metastasis; underlying disease which can't receive chemotherapy; known contraindication for chemotherapy agent (taxan reaction); severe cardiac problem history such as heart failure, chest pain which needs medication, severe cardiac valve disease, myocardial infarction, uncontrolled blood pressure (systolic pressure above 180 mm/Hg and diastolic pressure above 100 mm/Hg); refusing treatment by patient.

### Age

From **20 years** old to **75 years** old

### Gender

Both

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **70**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single blinded

### Blinding description

### Placebo

Not used

### Assignment

Parallel

### Other design features

Table of random numbers

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

**Name of ethics committee**

Ethics committee of Shiraz medical university

**Street address**

Zand street; Shiraz medical university

**City**

Shiraz

**Postal code**

71937-11351

**Approval date**

2014-05-17, 1393/02/27

**Ethics committee reference number**

9101014880

## Health conditions studied

### 1

**Description of health condition studied**

Breast cancer

**ICD-10 code**

c50-c50

**ICD-10 code description**

Malignant neoplasm of breast

## Primary outcomes

### 1

**Description**

Clinical response

**Timepoint**

Before treatment start and every 3 weeks for 4 cycle after treatment

**Method of measurement**

Caliper measurement (millimeter)

### 2

**Description**

Radiologic response

**Timepoint**

Before treatment and 3 month after chemotherapy

**Method of measurement**

Sonography

### 3

**Description**

Pathologic response

**Timepoint**

3 months later after chemotherapy followed by surgery

**Method of measurement**

Pathologic size (millimeter)

## Secondary outcomes

### 1

**Description**

Bone marrow suppression

**Timepoint**

Before chemotherapy and every 3 weeks after chemotherapy

## Method of measurement

Lab data

### 2

**Description**

Extrimity edema

**Timepoint**

Before chemotherapy and every 3 weeks after chemotherapy

**Method of measurement**

History and physical exam

### 3

**Description**

Alopecia

**Timepoint**

Before chemotherapy and every 3 weeks after chemotherapy

**Method of measurement**

History and exam

## Intervention groups

### 1

**Description**

For intervention group: from antimetabolite group; gemcitabine 1000 mg/m<sup>2</sup> in days 1 and 8 via intravenous injection in 30 minutes and paclitaxel 175 mg/m<sup>2</sup> from taxan group in day one via intravenous in 3 hours every 3 weeks for 4 cycle as neoadjuvant therapy if lab data is normal for preoperation.

**Category**

Treatment - Drugs

### 2

**Description**

For control group: from antracyclins group; doxorubicin 60 mg/m<sup>2</sup> in days 1 via intravenous injection in several minutes and cyclophosphamide 600 mg/m<sup>2</sup> from alkylene group in day one via intravenous in several minutes every 3 weeks for 4 cycle as neoadjuvant therapy if lab data is normal for preoperation.

**Category**

Treatment - Drugs

## Recruitment centers

### 1

**Recruitment center**

**Name of recruitment center**

Department of Radiation and Oncology of Shiraz Medical University

**Full name of responsible person**

Moaddab Shoar Leila

**Street address**

71937, Namazi Hospital, Namazi Square, Zand Street, Shiraz, Iran.

**City**  
Shiraz

**Email**  
moadabshoar@sums.ac.ir  
**Web page address**

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**  
Vice chancellor for research, Shiraz University of  
Medical Sciences

**Full name of responsible person**  
Masoompour Masoom

**Street address**  
seventh floor, 71345, Central construction, Shiraz  
University of Medical Sciences, Zand street, Shiraz,  
Iran.

**City**  
Shiraz

#### Grant name

-

#### Grant code / Reference number

-

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

Yes

#### Title of funding source

Vice chancellor for research, Shiraz University of Medical  
Sciences

#### Proportion provided by this source

100

#### Public or private sector

*empty*

#### Domestic or foreign origin

*empty*

#### Category of foreign source of funding

*empty*

#### Country of origin

#### Type of organization providing the funding

*empty*

## Person responsible for general inquiries

#### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Leila Moaddab Shoar

**Position**  
Radiation Oncologist

#### Other areas of specialty/work

**Street address**  
71937, Namazi Hospital, Namazi Square, Zand Street,  
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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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**Position**  
Radiation Oncologist

#### Other areas of specialty/work

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## Person responsible for updating data

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**Name of organization / entity**  
Shiraz University of Medical Sciences

**Full name of responsible person**  
Leila Moaddab Shoar

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#### Web page address

## Sharing plan

#### Deidentified Individual Participant Data Set (IPD)

*empty*

#### Study Protocol

*empty*

#### Statistical Analysis Plan

*empty*  
**Informed Consent Form**  
*empty*  
**Clinical Study Report**  
*empty*

**Analytic Code**  
*empty*  
**Data Dictionary**  
*empty*