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; underling disease which can’t receive chemotherapy; known contraindication for chemotherapy agent (taxan reaction); sever cardiac problem history such as heart failure, chest pain which needs medication, sever 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/m2 and Cyclophosphamide 600 mg/m2 on the first day and in the other arm Gemcitabine 1000 mg/m2, days 1 and 8, Paclitaxel 175 mg/m2 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 Univercity of Medical Science

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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 chemotherpy 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; underling disease which can’t receive chemotherapy; known contraindication for chemotherapy agent (taxan reaction); sever cardiac problem history such as heart failure, chest pain which needs medication, sever 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

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

Method of measurement

Caliper measurment (milimeter)

2

Description

Radiologic response

Timepoint

Befor treatment and 3month after chemotherapy

Method of measurement

Sonography

3

Description

Pathologic response

Timepoint

3 months later after chemotherapy followed by surgery

Method of measurement

Pathologic size (milimeter)

Secondary outcomes

1

Description

Bone marrow suppression

Timepoint

Befor chemotherpy and every 3 weeks after chemotherapy

Method of measurement

Lab data

2

Description

Extrimity edema

Timepoint

Befor chemotherpy and every 3 weeks after chemotherapy

Method of measurement

History and physical exam

3

Description

Alopecia

Timepoint

Befor chemotherpy 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/m2 in days 1 and 8 via intravenous injection in 30 minutes and paclitaxel 175 mg/m2 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/m2 in days 1 via intravenous injection in several minutes and cyclophosphamide 600 mg/m2 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

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
Radiatiion Oncologist
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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