

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Evaluation of clinical and histopathological efficacy of carboplatin and gemcitabine as second line neoadjuvant therapy in locally advanced breast cancer patients

Protocol summary

Summary

This study is conducted in 50 subjects diagnosed with locally advanced breast cancer. Neoadjuvant chemotherapy in such tumors is basically used to reduce tumor size. The standard neoadjuvant regimen used, is the combination of doxorubicin, cyclophosphamide and paclitaxel. End point of neoadjuvant chemotherapy is reaching pathologic complete response (pCR). Generally regardless of the neoadjuvant regimen, pCR, considered as a prognostic factor for response to therapy, has been estimated to be 3-46% in different studies. Since pCR can be relevant to patients' survival rate, efforts to increase this parameter can be beneficial for the patient. The aim of this study is to evaluate a second line neoadjuvant chemotherapy with the hope of increasing pCR in patients that have not reached a complete clinical response after the standard neoadjuvant regimen. Patient's clinical status and sonography data are parameters used for evaluating clinical response. According to previous studies and data proving the effectiveness of other agents, carboplatin and gemcitabine with the estimated dose of AUC x 5 and 1g/m² respectively have been selected as the second line regimen. Two to 3 cycles of second line therapy has been planned. Patients are randomly divided to control and intervention groups. The control group will be receiving the standard neoadjuvant chemotherapy and the intervention group will be treated with both standard and second line chemotherapy. The pathologist and statistical analyst will be blind towards studied groups of patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017100136491N1**

Registration date: **2017-11-19, 1396/08/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2017-11-19, 1396/08/28

Registrant information

Name

Dena Firouzabadi

Name of organization / entity

Shiraz university of medical sciences-School of Pharmacy-Pharmacotherapy department

Country

Iran (Islamic Republic of)

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+98 71 3242 4128

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firouzabad@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

This study was approved in the Pharmaceutical Sciences Research Center of Shiraz School of Pharmacy and the budget will therefore be provided from the same center.

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of clinical and histopathological efficacy of carboplatin and gemcitabine as second line neoadjuvant therapy in locally advanced breast cancer patients

Public title

Studying the effect of addition of carboplatin and gemcitabine to standard therapy in improving response rate in breast cancer patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Female patients; Diagnosed with locally advanced breast cancer; 18 to 60 years of age. Exclusion criteria: Evidence of metastasis; Inflammatory breast cancer; Abnormal kidney function (Serum creatinine > 1.5 mg/dl); Abnormal liver function (Bilirubin and Serum transaminase > 2xULN); Abnormal Bone marrow function (Abnormal hemoglobin, WBC and platelet count)

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Vice Chancellery of Research Affairs, Shiraz University of Medical Sciences

Street address

7th floor, Shiraz University of Medical Sciences central building, Next to the red crescent, Zand St.

City

Shiraz

Postal code

71345-1978

Approval date

2017-07-30, 1396/05/08

Ethics committee reference number

IR.SUMS.REC.1396.S372

Health conditions studied

1

Description of health condition studied

Breast cancer

ICD-10 code

C50

ICD-10 code description

Malignant neoplasm of breast

Primary outcomes

1

Description

Complete pathologic response

Timepoint

At the end of second line chemotherapy and surgery for the intervention group (approximately 4-6 months after start of therapy) and at the end of standard chemotherapy and surgery for the control group (approximately 4 months after start of therapy)

Method of measurement

histopathologic evaluation of tumoral tissue of the breast

Secondary outcomes

1

Description

Renal adverse effects

Timepoint

Measured monthly for both groups and at the end of the second line chemotherapy in the intervention group (approximately 4-6 months after start of therapy) and at the end of the standard chemotherapy for the control group (approximately 4 months after start of therapy)

Method of measurement

Serum creatinine measurement and calculation of glomerular filtration rate (GFR)

2

Description

Bone marrow suppression

Timepoint

Measured monthly for both groups and at the end of the second line chemotherapy in the intervention group (approximately 4-6 months after start of therapy) and at the end of the standard chemotherapy for the control group (approximately 4 months after start of therapy)

Method of measurement

complete blood count (white blood cells, hemoglobin, platelet)

Intervention groups

1

Description

Intervention group: Addition of second line neoadjuvant chemotherapy including Carboplatin intravenous injection with the dose of 5x target AUC and gemcitabine intravenous injection with the dose of 1 gram per square meter of body surface area, both for two to three cycles, to first line standard neoadjuvant chemotherapy.

Category

Treatment - Drugs

2

Description

Control group: Applying first line standard neoadjuvant chemotherapy including doxorubicin intravenous injection with the dose of 60 mg per square meter of body surface area along with cyclophosphamide intravenous injection with the dose of 600 mg per square meter of body surface area and paclitaxel intravenous injection with the dose of 175 mg per square meter of body surface area, all three applied for 4 cycles.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahhari Specialty Sub-specialty Clinic affiliated to Shiraz University of Medical Sciences

Full name of responsible person

Dr. Alireza Rezvani, Hematologist Oncologist, Assistant professor Shiraz University of Medical Scienc

Street address

Hematology clinic, 4th floor, Shahid Motahhari Specialty and Sub-specialty Clinic, Namazi square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ministry of Research, Shiraz University of Medical Sciences, Pharmaceutical Sciences Research Center

Full name of responsible person

Dr. Younes Ghasemi

Street address

Pharmaceutical Sciences Research Center, School of Pharmacy, Karafarin street, 5th kilometer of Shiraz Isfahan highway

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ministry of Research, Shiraz University of Medical Sciences, Pharmaceutical Sciences Research Center

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

Pharmacotherapy Department, School of Pharmacy, Shiraz University of Medical Sciences

Full name of responsible person

Dr. Laleh Mahmoudi

Position

Pharmacist, Pharmacotherapist, Associate professor at Shiraz School of Pharmacy

Other areas of specialty/work

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Person responsible for scientific inquiries

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Associate professor

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Pharmacotherapy Department, School of Pharmacy-
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Full name of responsible person

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Postal code**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