Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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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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 Comittee 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 crecent, 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 measurment and calculation of glomerular filteration 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
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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
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Pharmacist, Pharmacotherapist, Associate professor at Shiraz School of Pharmacy
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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