Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Sep 2026

Clinical trial of Phase III of study of the efficacy of docetaxel and carboplatin with or without doxorubicin hydrochloride and cyclophosphamide in treating Iranian women with triple negative breast cancer: A adjuvant therapy study

Protocol summary

Summary

Objectives: The aim of this trial is to evaluate OS, PFS and toxicity of Arm A compared to Arm B after adjuvant therapy in untreated triple negative breast cancer patients with Iranian ethnicity. Setting : A randomized and clinical trial in University Hospital Design: The patients randomizely are divided to two groups: 60 patients in Arm A (treated with Docetaxel 70 mg/m2 and Carboplatin 7 AUC every three weeks with granulocyte colony-stimulating factor (G-CSF) for 6 course) and 59 patients in Arm B(treated with Doxorubicin Hydrochloride 60 mg/m2 and Cyclophosphamide 600mg/m2 every three weeks with G-CSF for 4 course followed by Docetaxel 70 mg/m2 and Carboplatin 7 AUC every three weeks with G-CSF for 4 course)), between Jul 2011 and Aug 2016. 2-and 5-year overall survival and progression-free survival and also adverse affects for every group are calculated. Participants including major eligibility criteria: Inclusion criteria: The tumor must have been determined to be human epidermal growth factor receptor (HER2)-negative;The tumor must have been determined to be hormonal receptor-negative (ER-and PR-negative) Exclusion criteria:T4 tumors including inflammatory breast cancer; Radiologic evidence of metastatic disease;Any previous history of ipsilateral invasive breast cancer or ipsilateral DCIS; History of non-breast malignancies; Active or History of cardiac disease; Patients known to be human immunodeficiency virus (HIV) positive; Active hepatitis B or hepatitis C with abnormal liver function tests;History of hospitalization in past 12 months for diabetes; Pregnancy or lactation at the time of study entry. Main outcome: Neutropenia,Vomiting,sepsis etc

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016070325791N2**
Registration date: **2016-08-06, 1395/05/16**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-08-06, 1395/05/16

Registrant information

Name

Masoud Sadeghi

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Kermanshah University of Medical Sciences

Expected recruitment start date

2011-02-01, 1389/11/12

Expected recruitment end date

2011-07-01, 1390/04/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Clinical trial of Phase III of study of the efficacy of docetaxel and carboplatin with or without doxorubicin hydrochloride and cyclophosphamide in treating Iranian women with triple negative breast cancer: A adjuvant therapy study

Public title
Treatment for women with triple negative breast cancer

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: The tumor must have been determined to be human epidermal growth factor receptor 2 (HER2)-negative;The tumor must have been determined to be hormonal receptor-negative (ER-and PR-negative) Exclusion criteria:T4 tumors including inflammatory breast cancer; Definitive clinical or radiologic evidence of metastatic disease; required imaging studies must have been performed within 90 days prior to randomization; Any previous history of ipsilateral invasive breast cancer or ipsilateral DCIS;History of non-breast malignancies (except for in situ cancers treated only by local excision and basal cell and squamous cell carcinomas of the skin) within 5 years prior to randomization;Active or History of cardiac disease;Patients known to be human immunodeficiency virus (HIV) positive; Active hepatitis B or hepatitis C with abnormal liver function tests;History of hospitalization in past 12 months for diabetes;Pregnancy or lactation at the time of study entry

Age
From **21 years** old to **85 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **119**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not 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 Kermanshah University of Medical Sciences

Street address
Kermanshah University of Medical Sciences, Shahid Beheshti Boulevard, Kermanshah, Iran

City
Kermanshah

Postal code

Approval date
2016-04-13, 1395/01/25

Ethics committee reference number
KUMS.REC.1395.2

Health conditions studied

1

Description of health condition studied
Triple negative breast cancer

ICD-10 code
C50.9

ICD-10 code description
Breast, unspecified

Primary outcomes

1

Description
Overall Survival

Timepoint
2- and 5-year

Method of measurement
Observation

2

Description
Progression-free Survival

Timepoint
2- and 5-year

Method of measurement
Observation

Secondary outcomes

1

Description
Neutropenia

Timepoint
every 21 days

Method of measurement
Experimental

2

Description
Grade 3-4 vomiting
Timepoint
every 21 days
Method of measurement
Experimental

3

Description
Grade 3-4 thrombocytopenia
Timepoint
every 21 days
Method of measurement
Experimental

4

Description
Peripheral neuropathy
Timepoint
every 21 days
Method of measurement
Experimental

Intervention groups

1

Description
Arm A:Docetaxel 70 mg/m2 and Carboplatin 7 AUS every three weeks with granulocyte colony-stimulating factor for 6 course
Category
Treatment - Drugs

2

Description
Arm B: Doxorubicin Hydrochloride 60 mg/m2 and Cyclophosphamide 600mg/m2 every three weeks with G-CSF for 4 course followed by Docetaxel 70 mg/m2 and Carboplatin 7 AUS every three weeks with G-CSF for 4 course
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Breast Cancer Research Center
Full name of responsible person
Dr. Safa Najafi
Street address
No.45, Gharbi Shahid Nazari St., Aborihan Av., Enghalab St.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University Of Medical Sciences and Health Services
Full name of responsible person
Dr. Behrooz Hamzeh
Street address
Kermanshah University Of Medical Sciences, Beheshti blv, kermanshah, iran Kermanshah Kermanshah Iran, Islamic Republic Of Kermanshah Kermanshah Iran, Islamic Republic Of
City
Kermanshah
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, Kermanshah University Of Medical Sciences and Health Services
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
Kermanshah University of Medical Sciences
Full name of responsible person
Masoud Sadeghi
Position
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Other areas of specialty/work
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Person responsible for scientific

inquiries

Contact

Name of organization / entity
Breast Cancer Research Center of Jahad Daneshgahi

Full name of responsible person
Dr. Safa Najafi

Position
Assistant professor

Other areas of specialty/work

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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