

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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+98 83 3842 5822

Email address

msadeghi@kums.ac.ir

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

MSc

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Breast Cancer Research Center of Jihad 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