

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Aug 2026

Comparison of PDlasta® (Pegfilgrastim) & PDgrastim® (Filgrastim) efficacy and safety in increasing absolute neutrophil count in breast cancer patients on adjuvant and neoadjuvant treatment with Dose-dense ac4-t4

Protocol summary

Study aim

Comparison of PDlasta & PDgrastim efficacy and safety in breast cancer patients on adjuvant and neoadjuvant treatment with Dose-dense ac4-t4 (Doxorubicin-Cyclophosphamide-Paclitaxel)

Design

Randomized, interventional, two arm parallel group, single blind clinical trial

Settings and conduct

Patients will be randomly assigned to the drug group (PDlasta) or to the control group (PDgrastim), after having recorded all the necessary information in their case, if they have indications of GCSF. These drugs are given free of charge. Patients in the two groups will receive up to 8 courses each time they undergo chemotherapy. In the next step, the patients' response to these treatments and the possible side effects of the drug are examined and in addition to the baseline, on days 7 and 14, ANC (Absolute neutrophil count) is examined. (Place of study: Clinic of breast cancer)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Breast cancer patients candidate of adjuvant and neoadjuvant therapy older than 18 years ;Exclusion criteria: Bilirubin > upper limit of normal; or aspartate transaminase and/or alanine transaminase >1.5 × upper limit of normal, concomitant with alkaline phosphatase >2.5 × upper limit of normal, radiation therapy within 4 weeks of randomization into this study, prior bone marrow or stem cell transplantation, total lifetime exposure to doxorubicin >240 mg/m² or epirubicin >600 mg/m², EF<40%, liver cirrhosis

Intervention groups

Patients receive a single subcutaneous injection of 6 mg of PDlasta during each chemotherapy cycle on the first day after receiving chemotherapy (24 hours later). In the control group, PDgrastim is given as a subcutaneous

injection of 300 micrograms per day for six consecutive days.

Main outcome variables

Change of ANC at the beginning of each chemotherapy course, Determine the frequency of possible side effects in the process of treatment

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190504043465N1**

Registration date: **2019-05-18, 1398/02/28**

Registration timing: **retrospective**

Last update: **2019-05-18, 1398/02/28**

Update count: **0**

Registration date

2019-05-18, 1398/02/28

Registrant information

Name

Sina Ebrahimi

Name of organization / entity

Pooyesh Darou

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-09-15, 1395/06/25

Expected recruitment end date

2018-12-16, 1397/09/25

Actual recruitment start date

2016-10-16, 1395/07/25

Actual recruitment end date

2019-01-15, 1397/10/25

Trial completion date

2019-02-14, 1397/11/25

Scientific title

Comparison of PDlasta® (Pegfilgrastim) & PDgrastim® (Filgrastim) efficacy and safety in increasing absolute neutrophil count in breast cancer patients on adjuvant and neoadjuvant treatment with Dose-dense ac4-t4

Public title

Efficacy and safety of PDlasta® and PDgrastim® in breast cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Investigator diagnosis of breast cancer candidate of adjuvant and neoadjuvant therapy Absolute neutrophil count $\geq 1.5 \times 10^9/L$ Platelet count $\geq 100 \times 10^9/L$ Serum creatinine $< 1.5 \times$ upper limit of normal Dose-dense ac4-t4 regimen

Exclusion criteria:

Bilirubin $>$ upper limit of normal; or Aspartate transaminase and/or Alanine transaminase $> 1.5 \times$ upper limit of normal, concomitant with Alkaline phosphatase $> 2.5 \times$ upper limit of normal Radiation therapy within 4 weeks of randomization into this study Prior bone marrow or stem cell transplantation Total lifetime exposure to Doxorubicin > 240 mg/m² or Epirubicin > 600 mg/m² Ejection fraction $< 40\%$ Liver cirrhosis

Age

From 18 years old

Gender

Female

Phase

3

Groups that have been masked

- Data analyser

Sample size

Target sample size: 80

Actual sample size reached: 80

Randomization (investigator's opinion)

Randomized

Randomization description

For random allocation of participants into two arm of treatments, the permuted block randomization was used with quadruple blocks. According to the identified sample size of 80, twenty blocks were produced. Four persons of each group were randomly and equally assigned to treatment A or B using a toss. In order to apply the concealment in the randomization process, 20 thick pocket were selected randomly by the software (www.sealedenvelope.com). By this method, nobody was

aware of allocation sequence of participants to treatment groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

Due to the different protocol of prescribing two drugs and the necessity of monitoring an oncologist, there is no possibility of blinding the patient and the therapist. The results analyst specialist will not be informed about how people are assigned to groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Jahad Daneshgahi breast cancer institute

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Approval date

2016-10-16, 1395/07/25

Ethics committee reference number

IR.ACECR.IBCRC.REC.139.19

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**

Absolute Neutrophil Count

Timepoint

Before intervention (baseline), 7th day and 14th day after each chemotherapy course

Method of measurement

Blood sample

2**Description**

White blood cell

Timepoint

Before intervention (baseline), 7th day and 14th day after each chemotherapy course

Method of measurement

Blood sample

Secondary outcomes**1****Description**

Febrile neutropenia

Timepoint

7th day and 14th day after each chemotherapy course

Method of measurement

Clinical evaluation

Intervention groups**1****Description**

Intervention group: Patients receive the subcutaneous injection of 6 mg of Pegfilgrastim (PDlasta) in each chemotherapy cycle (on the first day after chemotherapy (24 hours later).

Category

Treatment - Drugs

2**Description**

Control group: Patients on the first day after chemotherapy (24 hours later) will use Filgrastim (PDgrastim) for subcutaneous injection of 300 micrograms daily for six consecutive days.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Breast cancer research center

Full name of responsible person

Safa Najjar Najafi

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Web page address<http://ibcrc.ir/>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

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Web page address<https://pooyeshdarou.com/>**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Pooyesh Darou

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding*empty***Country of origin****Type of organization providing the funding**

Persons

Person responsible for general inquiries**Contact****Name of organization / entity**

Breast Cancer Research Center

Full name of responsible person

Safa Najjar Najafi

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Hematology

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available