Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Oct 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/m^2 or epirubicin >600 mg/m^2, 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)

Phone
+98 21 8897 0979

Email address
ebrahimi@pooyeshdarou.com

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 ≥1.5 × 10^9/L Platelet count ≥100 × 10^9/L Serum creatinine <1.5 × 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 × 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 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
Street address
No. 45, West Shahid nazari Ave, Aboureyhan St, Enghelab e eslami St
City
Tehran
Province
Tehran
Postal code
1315685981
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
Street address
No. 45, West Shahid nazari Ave, Aboureyhan St, Enghelab e eslami St
City
Tehran
Province
Tehran
Postal code
1315685981
Phone
+98 21 6640 4050
Email
ibcrc@acecr.ac.ir
Web page address
http://ibcrc.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Pooyesh Darou
Full name of responsible person
Sina Ebrahimi
Street address
No.13, 5th Ave, Fatemi St
City
Tehran
Province
Tehran
Postal code
1415763863
Phone
+98 21 8897 0979
Fax
+98 21 8896 9368
Email
Ebrahimi@pooyeshdarou.com
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
Street address
No. 45, West Shahid nazari Ave, Aboureyhan St, Enghelab e eslami St
City
Tehran
Province
Tehran
Postal code
1315685981
Phone
+98 21 6640 4050
Email
Safa3n@yahoo.com

Person responsible for scientific 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
Street address
No. 45, West Shahid nazari Ave, Aboureyhan St, Enghelab e eslami St
City
Tehran
Province
Tehran
Postal code
1315685981
Phone
+98 21 6640 4050
Email
Safa3n@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Pooyesh Darou
Full name of responsible person
Sina Ebrahimi
Position
Clinical trials supervisor
Latest degree
Medical doctor
Other areas of specialty/work
Pharmacovigilance
Street address
No.13, 5th Ave, Fatemi St, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1415763863
Phone
+98 21 8897 0979
Fax
Email
ebrahimi@pooyeshdarou.com

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