

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

A Non-randomized, Single-armed Clinical trial study to determine the therapeutic efficacy of Pegfilgrastim (CinnaGen Company) to treatment of anemia consequent taxans chemotherapy in breast cancer patients

Protocol summary

Summary

The primary objective of this study was evaluation of efficacy and safety of Pegfilgrastim (PegaGen®, CinnaGen Co.) in treatment of hematological adverse events due to the administration of taxane-based chemotherapy in breast cancer patients. The intended population included breast cancer woman patients aged less than 65 and with cancer stages I-III. Patients with metastatic disease, hepatic impairment, myelosuppression, pregnancy or breastfeeding were excluded from the trial. All of patients received the standard chemotherapy regimen according to treatment protocol of breast cancer institute, consisting of 4 cycles of Adriamycin plus cyclophosphamide followed by 4 cycles of Taxotere. A 6-mg single dose injection of Pegfilgrastim was administered in the beginning of each cycle to improve the hematological profile in patients. Hematological profile was assessed for all patients before each chemotherapy cycle. The main objective was the frequency of neutropenia of less than 1000 per micro-liter in patient CBC test. In addition, the frequency of bone pain, injection site pain, injection site reactions, thrombocytopenia, fever and hospitalization were evaluated. All patients were followed and assessed from the time of randomization until 2 weeks after the last chemotherapy cycle.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017012121315N7**

Registration date: **2017-03-12, 1395/12/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-12, 1395/12/22

Registrant information

Name

Nassim Anjidani

Name of organization / entity

Orchid Pharmed

Country

Iran (Islamic Republic of)

Phone

+98 21 4347 3000

Email address

amini@orchidpharmed.com

Recruitment status

Recruitment complete

Funding source

CinnaGen Company

Expected recruitment start date

2012-08-09, 1391/05/19

Expected recruitment end date

2013-06-22, 1392/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Non-randomized, Single-armed Clinical trial study to determine the therapeutic efficacy of Pegfilgrastim (CinnaGen Company) to treatment of anemia consequent taxans chemotherapy in breast cancer patients

Public title

The effect of Pegfilgrastim on treatment of anemia consequent taxans chemotherapy in breast cancer

patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: breast cancer stage I-III and women between the age of 18-65 years at the time of signing the informed consent form. Exclusion criteria: patients with metastatic breast cancer; liver failure or myelosuppression; pregnancy or lactation and dissatisfaction.

Age
From **18 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **75**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Avicenna Research Institute

Street address

Avicenna Research Institute, Inside Shahid Beheshti University of Medical Sciences, Velenjak), Street Yemen, Street Din Fadl Allah, the martyr Beheshti University

City

Tehran

Postal code

1177-19615

Approval date

2012-05-22, 1391/03/02

Ethics committee reference number

91/15/881/ص

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C50.9

ICD-10 code description

Malignant neoplasm of breast of unspecified site

2

Description of health condition studied

Neutropenia

ICD-10 code

D70

ICD-10 code description

Neutropenia

Primary outcomes

1

Description

pegfilgrastim efficacy at grade 3 and 4 neutropenia from second cycle at chemotherapy regimen include taxans at breast cancer

Timepoint

Every two weeks until two weeks after the last dose of pegfilgrastim

Method of measurement

Cell Blood Count (CBC)

Secondary outcomes

1

Description

Determining the frequency of grade 3 and 4 neutropenia

Timepoint

Every two weeks until two weeks after the last dose of pegfilgrastim

Method of measurement

Cell Blood Count (CBC)

2

Description

Determining the frequency of bone pain

Timepoint

Every two weeks until two weeks after the last dose of pegfilgrastim

Method of measurement

patient assessment

3

Description

Determining the frequency of injection site pain

Timepoint

Every two weeks until two weeks after the last dose of pegfilgrastim

Method of measurement

patient assessment

4

Description

Determining the frequency of injection site reaction

Timepoint

Every two weeks until two weeks after the last dose of pegfilgrastim

Method of measurement

Physician assessment

5

Description

Determining the frequency of thrombocytopenia

Timepoint

Every two weeks until two weeks after the last dose of pegfilgrastim

Method of measurement

CBC (Cell Blood Count)

6

Description

Determining the frequency of febrile neutropenia

Timepoint

Every two weeks until two weeks after the last dose of pegfilgrastim

Method of measurement

Physician assessment

7

Description

Determining the frequency of hospitalization

Timepoint

Every two weeks until two weeks after the last dose of pegfilgrastim

Method of measurement

Physician assessment

Intervention groups

1

Description

CinnaGen Pegfilgrastim (Prefilled syringe: 6 mg / 0.6 ml for SC Injection, Single Dose Every Two Weeks for 24 months)

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. 146, South Gandhi Ave, Vanak Sq, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

CinnaGen Company

Full name of responsible person

Ramin Azhdarzadeh

Street address

No.2, Khorasani Alley, Derakhti Ave, Dadman blvd, Shahrak-e-Gharb

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

CinnaGen Company

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

Orchid Pharmed Company

Full name of responsible person

Ramin Azhdarzadeh

Position

Pharmacist (PhD), Clinical Trial Manager

Other areas of specialty/work

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Person responsible for scientific

inquiries

Contact

Name of organization / entity

Breast Cancer Research Center, ACECR

Full name of responsible person

Safa Najjar Najafi

Position

Assistant professor of hematology-oncology

Other areas of specialty/work

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Full name of responsible person

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Position

Pharmacist (PhD), Clinical Trial Manager

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