Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Oct 2026

Comparison of the effects of Pegagen and G-csf in the chemotherapy induced cytopennia in the breast cancer patients

Protocol summary

Summary

24 women with newly diagnosed breast cancer underwent the dose dense chemotherapy regimen consisting of Taxoter, Cyclophosphamide and Adriamycine. The patients were assigned to two groups randomly. The first group was given single dose of 6 mg pegagen after the completion of the first course of chemotherapy, and the second course of chemotherapy was followed by daily subcutaneous injection of 300 ugr G-csf for 5 days. The second group was treated with G-csf after the first course of chemotherapy and was given pegagen following the second course. white blood cell,Hb, neutrophil and drugs side effects were compared in these patients before, one week and 2 weeks after the chemotherapy

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017020732444N1**
Registration date: **2017-03-30, 1396/01/10**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-03-30, 1396/01/10

Registrant information

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Mehrzad Salmasi
Name of organization / entity
Isfahan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source
Isfahan University of Medical Sciences

Expected recruitment start date

2015-09-28, 1394/07/06

Expected recruitment end date

2017-03-20, 1395/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effects of Pegagen and G-csf in the chemotherapy induced cytopennia in the breast cancer patients

Public title

Comparison of the effects of Pegagen and G-csf in the treatment of cytopenia induced by breast cancer chemotherapy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age >18 years old; absolute neutrophil count ≥1.5 × 109/l; platelet count ≥100 × 109/l; serum creatinine <1.5 × upper limit of normal. Exclusion criteria: hypersinsitivity reaction; unwillingness of patients to continue; change of chemotherapy regimen.

Age

From **18 years** old

Gender

Both

Phase

N/A
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
cross over clinical trial

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jerib street
City
Isfahan
Postal code
8158177356
Approval date
2015-05-22, 1394/03/01
Ethics committee reference number
IR.MUI.REC.1395.3.546

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
neutrophil count
Timepoint
before chemothrapy and 1 weeks and 2 weeks later
Method of measurement
laboratory CBC

2

Description
Hb level
Timepoint
before chemothrapy and 1 weeks and 2 weeks later
Method of measurement
laboratory CBC

3

Description
platelet count
Timepoint
before chemothrapy and 1 weeks and 2 weeks later
Method of measurement
laboratory CBC

4

Description
drug reaction
Timepoint
before chemothrapy and 1 weeks and 2 weeks later
Method of measurement
questionnaire

5

Description
wbc count
Timepoint
before chemothrapy and 1 weeks and 2 weeks later
Method of measurement
laboratory CBC

Secondary outcomes

1

Description
fever
Timepoint
before chemotherapy and 1 week and 2 weeks later
Method of measurement
questionnaire

2

Description
abdominal pain
Timepoint
before chemotherapy and 1 week and 2 weeks later
Method of measurement
questionnaire

3

Description
dyspnea
Timepoint

before chemotherapy and 1 week and 2 weeks later
Method of measurement
questionnaire

4

Description
bone pain
Timepoint
before chemotherapy and 1 week and 2 weeks later
Method of measurement
questionnaire

5

Description
hypersensitivity reactions
Timepoint
before chemotherapy and 1 week and 2 weeks later
Method of measurement
questionnaire

6

Description
postpone chemotherapy
Timepoint
2 weeks after chemotherapy
Method of measurement
questionnaire

Intervention groups

1

Description
first group: single dose of 6 mgr Pegagen used after the completion of first course of chemotherapy and 300 ugr G-csf daily for 5 days used at the end of the second course
Category
Treatment - Drugs

2

Description
second group: after completion of the first course of chemotherapy 300 ugr G-csf daily for 5 days used and at the end of the second course single dose of 6 mgr Pegagen used
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Omid hospital
Full name of responsible person
Farzane Ashrafi
Street address
Motahari street
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Isfahan University of Medical Sciences
Full name of responsible person
Mrs Mazaheri
Street address
Isfahan University of Medical Sciences, Daneshgah street
City
Isfahan
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, Isfahan University of Medical Sciences
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
Isfahan University of Medical Sciences
Full name of responsible person
Mehrzad Salmasi
Position
MD/ Resident of internal medicine
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Person responsible for scientific inquiries

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Farzane Ashrafi

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Professor of hematology and oncology

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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