# 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**

**Name**
Mehrzad Salmasi
**Name of organization / entity**
Isfahan University of Medical Sciences
**Country**
Iran (Islamic Republic of)
**Phone**
+98 31 3263 0366
**Email address**
m.salmasi@resident.mui.ac.ir

**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
**Other areas of specialty/work**
**Street address**
Azahra hospital
**City**
Isfahan
**Postal code**
**Phone**
+98 31 3263 0366
**Fax**
**Email**
mehrzad_salmasi@yahoo.com
**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Isfahan University of Medical Sciences

**Full name of responsible person**
Farzane Ashrafi

**Position**
Professor of hematology and oncology

**Other areas of specialty/work**

**Street address**
Omid hospital

**City**
Isfahan

**Postal code**

**Phone**
+98 31 3235 0214

**Fax**

**Email**
farashrafi@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Isfahan University of Medical Sciences

**Full name of responsible person**
Mehrzad Salmasi

**Position**
MD/ Residents of internal medicine

**Other areas of specialty/work**

**Street address**
Isfahan Azahra Hospital

**City**
Isfahan

**Postal code**

**Phone**
+98 31 3263 0366

**Fax**

**Email**
mehrzad_salmasi@yahoo.com

**Web page address**

## 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*