

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Aug 2026

Comparison of efficacy and adverse effects of filgrastim produced by Samen pharmaceutical company and neupogen as a standard drug in Breast Cancer Patients

Protocol summary

Summary

The aim of this study is comparison of efficacy and adverse effect of filgrastim produced by Samen company and Neupogen as a standard drug in breast cancer patients. 168 locally advanced breast cancer patients without neutropenia, hepatic and renal failure will enter in the randomized parallel double blind clinical trial. Patients will be stratified into two groups based on chemotherapy regimen then patients in each group will be randomized into two groups who will receive filgrastim produced by Samen Company or neupogen. The dose of each drug is 5 microgram/kg and will be administered 24 hours after chemotherapy for 5 days. Finally efficacy and adverse effects of drugs in each group will be evaluated based on clinical, preclinical and laboratory findings. Frequency of neutropenia, duration of neutropenia and adverse effects will compare between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206279801N3**
Registration date: **2013-12-19, 1392/09/28**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-12-19, 1392/09/28

Registrant information

Name

Amir Hooshang Mohammadpour

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 1882 3255

Email address

mohamadpoorah@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Samen Company

Expected recruitment start date

2013-12-22, 1392/10/01

Expected recruitment end date

2014-12-22, 1393/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy and adverse effects of filgrastim produced by Samen pharmaceutical company and neupogen as a standard drug in Breast Cancer Patients

Public title

Comparison of filgrastim produced by Samen Pharmaceutical Company and Neupogen as a standard drug

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age > 18 yr; Diagnosis of locally advanced breast cancer; WHO Performance Status less than or equal to 2; Absence of neutropenia (ANC < 1500/mm³) before starting chemotherapy; Completing the Consent form. Exclusion criteria: History of

hypersensitivity reaction to biologic drugs; Existence of renal failure ; Existence of hepatic failure ; Coadministration of neutropoietic drugs; Existence of cardiac arrhythmia.

Age

From **18 years** old to **80 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **168**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Mashhad University of Medical Sciences

Street address

Ethic committee of Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah street

City

Mashhad

Postal code

91375-345

Approval date

2009-01-19, 1387/10/30

Ethics committee reference number

5/10492

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

duration of neutropenia

Timepoint

between day 1 to day 21 post chemotherapy

Method of measurement

laboratory

Secondary outcomes

1

Description

frequency of neutropenia episode

Timepoint

between day 1 to 21 post chemotherapy

Method of measurement

laboratory

Intervention groups

1

Description

Samen GCSF (5 microgram/kg for 5 days 1 day after chemotherapy)

Category

Treatment - Drugs

2

Description

NEUPOGEN (5 microgram/kg for 5 days , 1 day after chemotherapy)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza chemotherapy center

Full name of responsible person

Dr. Fatemeh Homaei

Street address

No2, Fallahi street, Ghasem abad

City

Mashhad

2

Recruitment center

Name of recruitment center

Omid Hospital

Full name of responsible person

Dr.Fatemeh Homaei

Street address

Alanandash Square, Koohsangy street, Omid Hospital
City
Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Samen Pharmaceutical Company
Full name of responsible person
Dr. Hamid Mohammadpanah
Street address
17th Km Mashhad-Ghouchan Road
City
Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Samen Pharmaceutical 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
Samen Pharmaceutical Co.
Full name of responsible person
Dr. Mohammad Reza Ramezani
Position
Production Manager
Other areas of specialty/work
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Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Associate Professor
Other areas of specialty/work
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Person responsible for updating data

Contact

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Mashhad University of Medical Sciences
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Associate Professor
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