

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jun 2026

A therapeutic and side effects comparison between Rosastim and Brand type (Neupogen) in gastric cancer

Protocol summary

Summary

the goal of this open-label study is comparison between the Rosastim, the domestic product, and Neupogen, the brand type, in order to show the same efficiency in gastric cancers through two parallel groups. This study aims to reduce the costs and help patients to ease and availability of drugs, and plays the vital role in improving the local economy as well. Inclusion criteria are patients with gastric cancer from both sexes and exclusion criteria includes ill-informed patient consent for participation and hypersensitivity or other illness. Patients in each group treat with modified Ajani regimen. This diet includes Docetaxel, Cisplatin and Fluorouracil. The mentioned regimen repeats every three weeks and duration of treatment is six cycles that takes about 4-5 months. The capacity of sample is 60 patients and duration of study had predicted about 18 months.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014061118061N1**

Registration date: **2014-10-20, 1393/07/28**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-10-20, 1393/07/28

Registrant information

Name

Mehdi Mohammadzadeh

Name of organization / entity

Behin Tamin Rosamed Co.

Country

Iran (Islamic Republic of)

Phone

+98 21 8820 1982

Email address

info@iapme.ir

Recruitment status

Recruitment complete

Funding source

Behin Tamin Rosamed Co.

Expected recruitment start date

2013-04-20, 1392/01/31

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A therapeutic and side effects comparison between Rosastim and Brand type (Neupogen) in gastric cancer

Public title

A therapeutic and side effects comparison between domestic type and the similar brand in gastric cancer.

Purpose

Health service research

Inclusion/Exclusion criteria

inclusion criteria: 1. Patients with gastric cancers, age 18-65, both sexes 2. Biopsy and pathology results 3. Filling the consent form through patients or guardian 4. Possible cooperation of patients till the study completed.

exclusion criteria: 1. Ill-informed patient consent for participation in the study 2. Initial CBC disruption, so that lead to the wrong result in lab tests 3. Hypersensitivity to one type of Granulocyte Colony Stimulating Factor 4. History of treated malignancy or co-current malignancy 5. Patient may require radiation during treatment 6. Recurrent gastric cancer or refractory one that have

previously been treated 7. Inappropriate performance status for start or continue treatment 8. Mental illness or depression such that the compliance reduce.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

šhahid Beheshti University of Medical Science

Street address

Taleghani Hospital, Velenjak Ave.

City

Tehran

Postal code

1985717443

Approval date

2013-04-28, 1392/02/08

Ethics committee reference number

400/532

Health conditions studied

1

Description of health condition studied

Gasteric cancer

ICD-10 code

C16

ICD-10 code description

Malignant neoplasm of stomach

Primary outcomes

1

Description

White Blood Cell / Platlet / Hemoglobin measurement

Timepoint

triweekly

Method of measurement

Blood sample and Cell Blood Count measurement

Secondary outcomes

1

Description

CRAMP OF LOWER LIMB , Balance cerebellar

Timepoint

triweekly

Method of measurement

Check up

Intervention groups

1

Description

Neupogen prefilled syringe 300 microgram per 0.5 mL is as a control group, duration of treatment for each patient is about six months. blood sampling is done consecutive days, then one day is rest, after that sampling is done every other day. this process repeats triweekly till eight times.

Category

Treatment - Drugs

2

Description

Rosastim 300ug/0.5mL is a subcutaneous prefilled syringe. duration of treatment for each patient is about six months. blood sampling is done consecutive days, then one day is rest, after that sampling is done every other day. this process repeats triweekly till eight times.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Taleghani Hospitl

Full name of responsible person

Dr Babak Salimi

Street address

Velenjak Ave.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Behin Tamin Rosamed Co.

Full name of responsible person

Dr Mehdi Mohammadzadeh

Street address

No.82, Nasser St,Valie asr St,Tehran, Iran

City

Tehran

Grant name

خصوصی

Grant code / Reference number

ندارد

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

Yes

Title of funding source

Behin Tamin Rosamed Co.

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**

Taleghani Hospital

Full name of responsible person

Dr Babak Salimi

Position

Oncologist

Other areas of specialty/work**Street address**

Velenjak Ave. Taleghani hospital

City

Tehran

Postal code**Phone**

+98 21224325609

Fax**Email**

babak_salimd@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact**Name of organization / entity**

Shahidbeheshti University of Medical Science

Full name of responsible person

Dr Hamid Rezvani

Position

fellowship

Other areas of specialty/work**Street address**

Velenjak Ave.

City

Tehran

Postal code**Phone**

+98 21230311

Fax**Email**

info@rosamed-co.com

Web page address

Person responsible for updating data

Contact**Name of organization / entity**

Behin Tamin Rosamed Co.

Full name of responsible person

Reihaneh Karimi

Position**Other areas of specialty/work****Street address****City**

Tehran

Postal code

1968613135

Phone

+98 21 8865 0901

Fax

+98 21 8820 1984

Email

reihane.karimidastjerdi@yahoo.com
info@iapme-co.com
najva.kashani@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