Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

A phase III, Randomized, two armed, parallel, double blind Controlled non inferiority clinical Trial of Tinapeg(Produced by AryaTinaGene.) versus Neulastim for Preventing Chemotherapy induced Febrile Neutropenia in breast Cancer Patients

Protocol summary

Summary

This randomized, parallel, double blind controlled non inferiority phase III clinical trial is conducted to compare the effectiveness, safety and tolerability of Tinapeg® (a pegfilgrastim product of AryaTinaGene) versus Neulastim® after 4 cycle of chemotherapy in patients with breast cancer. Twenty four hours after chemotherapy, 100 patients aged 18 to 70 years who have high risk stage 2 or more of breast cancer and need chemotherapy will randomly divided into two groups and subcutaneously will receive Tinapeg® or Neulastim®. Cell blood counts will be performed in the beginning and 14 days after chemotherapy. The side effects and duration of neutropenia and hospitalization due to adverse drug reactions as well as the delay in starting the next cycle of chemotherapy will be recorded. Finally, collected data will be analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017061234487N1**
Registration date: **2017-06-29, 1396/04/08**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-06-29, 1396/04/08

Registrant information

Name

Mohammad Ali Afshari

Name of organization / entity

Aria Tinagene of knowledge-based company

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

AryaTinaGene Biopharmaceutical Company

Expected recruitment start date

2017-07-23, 1396/05/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A phase III, Randomized, two armed, parallel, double blind Controlled non inferiority clinical Trial of Tinapeg(Produced by AryaTinaGene.) versus Neulastim for Preventing Chemotherapy induced Febrile Neutropenia in breast Cancer Patients

Public title

A phase III, clinical Trial of Tinapeg(Produced by AryaTinaGene.) versus Neulastim for Preventing Chemotherapy induced Febrile Neutropenia in breast Cancer Patients

Purpose

Treatment

Inclusion/Exclusion criteria

Prevention Inclusion criteria for patients in detail, is defined as follows 1. Confirm the diagnosis of breast cancer pathology 2- 1-4 stage diagnosed by NCCN guideline requires chemotherapy regimens have AC. 3. Age between 18 to 70 years 4. The probability of pregnancy in female patients who have them must somehow fit during pregnancy, they avoid chemotherapy (using reliable contraception). Postmenopausal women at least 12 months have passed menopause, they do not need to take care of contraception. 5. Lack of symptomatic infection and fever specialist physician colleague 6. Adequate bone marrow activity is defined as follows: leukocytes >/=3,000/µl absolute neutrophil count >/=1,500/µl hemoglobin >/=8.0g/dl platelets >/=100,000/µl total bilirubin and serum creatinine must be < 1.5 mg/dl. 7. Adequate ability to read and understand the informed consent and to enter the study voluntarily and to sign the form. Exclusion criteria for patients in detail, is defined as follows: 1. The patient has received systemic chemotherapy before entering the study. 2. Undergoing major surgery during the past 4 weeks. 3. History of uncontrolled seizures, coma, psychological disorders or any other disorder that may decrease the patient ability to decide and sign the form. 4. Presence of any serious and uncontrolled diseases such as active infection, congestive heart failure, variant angina pectoris, cardiac arrhythmia. 5. Pregnancy or breast-feeding.

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **100**

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
Tehran university of medical science

Street address
Keshavarz Blv. QODES sT.

City
Tehran

Postal code
1455346878

Approval date
2017-05-31, 1396/03/10

Ethics committee reference number
IR.TUMS.VCR.REC 1396.2481

2

Ethics committee

Name of ethics committee
Gorgan university of medical science

Street address
Gorgan

City
Gorgan

Postal code
1455346878

Approval date
2017-05-31, 1396/03/10

Ethics committee reference number
IR.GOUMS.REC.1396.22

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C50

ICD-10 code description
Breast cancer

Primary outcomes

1

Description
In this clinical trial, equality, the absolute number of neutrophils per cubic millimeter of blood is frequently used as little

Timepoint
14 days after administration of the drug in the 4 cycles of chemotherapy

Method of measurement
blood test

Secondary outcomes

1

Description
1- neutropenic fever (fever over 38.5 degrees for at least an hour, as well as neutropenia less than 500 per cubic millimeter fever occurs on the same day) during each cycle of chemotherapy as well as a total of 4 cycles of chemotherapy. The index at the end of each cycle of chemotherapy in the form of data collection is recorded.

2. The number of days of severe neutropenia.5-severe neutropenia (absolute number of neutrophils less than 500 per microliter) in patients on the thirteenth day of each chemotherapy cycle 6-neutropenic average (absolute number of neutrophils between 500 to 1000 per microliter) in patients on the thirteenth day each cycle of chemotherapy 7-mild neutropenia (absolute neutrophil count 1,000 to 1,500 per microliter) On the thirteenth of each cycle of chemotherapy in patients neutrophil count based on blood samples and 8-cell count measured on the thirteenth day of each chemotherapy cycle, in the form of data collection is recorded.

Timepoint

After each cycle of chemotherapy and 24 hours after administration of study drug

Method of measurement

Tests for blood and neutrophil count

Intervention groups

1

Description

Neolastim control drug injection 24 hours after each cycle of chemotherapy

Category

Treatment - Drugs

2

Description

Tina peg intervention drug injection 24 hours after each cycle of chemotherapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shariati Hospital

Full name of responsible person

Dr Afshari

Street address

kargar shomali st. shokrollah St. no103

City

Tehran

2

Recruitment center

Name of recruitment center

Namazi Hospital

Full name of responsible person

Dr Afshari

Street address

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City

Shiraz

3

Recruitment center

Name of recruitment center

5 Azar Hospital

Full name of responsible person

Dr Afshari

Street address

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City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AryaTinaGene Biopharmaceutical Company

Full name of responsible person

Dr Majid Shahbazi

Street address

Sazandegi2 St.

City

Aq Qala

Grant name

111

Grant code / Reference number

110

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

Yes

Title of funding source

AryaTinaGene Biopharmaceutical 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

AryaTinaGene of knowledge-based company

Full name of responsible person

Dr Mohammad Ali Afshari

Position

PhD

Other areas of specialty/work

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Person responsible for scientific inquiries

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Person responsible for updating data

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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