Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Study of the Pharmacokinetic and Pharmacodynamic and Safety Properties of Tinagrast® (300 µg/0.5 ml Syringes, AryaTinaGene Biopharmaceutical Co) in Comparison to Neupogen® (300 µg/0.5 ml syringes, Amgen) in Healthy Volunteers

Protocol summary

Study aim
This study is designed to compare the biosimilarity of Tinagrast® and Neupogen® in healthy volunteers.

Design
This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacodynamic and pharmacokinetic of filgrastim from two different products in 24 healthy adults male volunteers.

Settings and conduct
The dose injection and subsequent sample collection will be performed in S. Motahhari hospital (Gonbade Kavous, Iran).

Participants/Inclusion and exclusion criteria
Inclusion criteria: Males, 18-50 years of age. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. The subject has stable residence and telephone. Good health at screening. Exclusion criteria: History of any drug hypersensitivity or intolerance Significant history or current evidence of chronic disease Receipt of any drug as part of a research study within 30 days prior to dosing. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to dosing.

Intervention groups
A single SC dose of filgrastim produced by AryaTinaGene Biopharmaceutical Co. and Amgen Inc.

Main outcome variables
1. Pharmacokinetic: Plasma concentration; Area under serum concentration-time curve 2. Pharmacodynamic: Absolute neutrophil count; Area under absolute neutrophil count-time curve

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130626013776N7**
Registration date: **2018-07-09, 1397/04/18**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-09, 1397/04/18**
Update count: **0**

Registration date
2018-07-09, 1397/04/18

Registrant information

Name
Hossein Amini

Name of organization / entity
Golestan University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 17 1442 1651

Email address
hamini@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-04-09, 1397/01/20

Expected recruitment end date
2018-07-11, 1397/04/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Study of the Pharmacokinetic and Pharmacodynamic and Safety Properties of Tinagrast® (300 µg/0.5 ml Syringes, AryaTinaGene Biopharmaceutical Co) in Comparison to Neupogen® (300 µg/0.5 ml syringes, Amgen) in Healthy Volunteers

Public title
Bioequivalence Study of Filgrastim in Healthy Human Volunteers
Purpose
Health service research
Inclusion/Exclusion criteria
Inclusion criteria:
Males, 18-50 years of age. The subject is able and willing to provide written informed consent. The subject is available for the entire study period and is willing to adhere to protocol requirements as evidenced by written informed consent. The subject has stable residence and telephone. Good health as determined by lack of clinically significant abnormalities in health assessments performed at screening.
Exclusion criteria:
History of allergy or sensitivity to filgrastim. history of any drug hypersensitivity or intolerance which, in the opinion of the investigator,would compromise the safety of the subject of the study. Significant history or current evidence of chronic infectious disease, system disorder or organ dysfunction. Presence of gastrointestinal disease or history of malabsorption within the last year. History of a medical disorders occurring within the last year that required hospitalization or medication Use of pharmacologic agents known to significantly induce or inhibit drug-metabolizing enzymes within 30 days prior to dosing. Receipt of any drug as part of a research study within 30 days prior to dosing. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to dosing.
Age
From **18 years** old to **50 years** old
Gender
Male

Phase
Bioequivalence
Groups that have been masked
No information
Sample size
Target sample size: **24**
Randomization (investigator's opinion)
Randomized
Randomization description
Each subject will be identified by a number from 1 to 24. Subjects were randomly allocated into 4 groups. Allocated groups: Group ID Volunteers ID number Sequence 1 1, 4, 6,7, 11&12 R/T 2 2, 3, 5, 8, 9, 10 &13 T/R 3 14, 15, 17, 21&22 T/R 4 16, 18, 19, 20, 23 &24 R/T The dosing regime will be as follows: Subjects Group Sequence Day 1 Day 8

_____ 1 1 R/T Reference Test 2 2 T/R Test Reference 3 2 T/R Test Reference 4 1 R/T Reference Test 5 2 T/R Test Reference 6 1 R/T Reference Test 7 1 R/T Reference Test 8 2 T/R Test Reference 9 2 T/R Test Reference 10 2 T/R Test Reference 11 1 R/T Reference Test 12 1 R/T Reference Test 13 2 T/R Test Reference 14 3 T/R Test Reference 15 3 T/R Test Reference 16 4 R/T Reference Test 17 3 T/R Test Reference 18 4 R/T Reference Test 19 4 R/T Reference Test 20 4 R/T Reference Test 21 3 T/R Test Reference 22 3 T/R Test Reference 23 4 R/T Reference Test 24 4 R/T Reference Test
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Golestan University of Medical Sciences
Street address
Gorgan, Shast cola road, Falsafi Building
City
Gorgan
Province
Golestan
Postal code
4916817693
Approval date
2018-06-17, 1397/03/27
Ethics committee reference number
IR.GOUMS.REC.1397.038

Health conditions studied

1

Description of health condition studied
Healthy volunteers
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Serum concentration of filgrastim
Timepoint
Before and 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 10 and 12 h after injection
Method of measurement
ELISA method with special kit

2

Description
Absolute neutrophil count
Timepoint
Before and at 4, 8, 10, 12, 16, 24, 36, 48, 72, and 96 h post-injection.
Method of measurement
Cell counter

Secondary outcomes

1

Description
Time to reach maximum serum concentration
Timepoint
Before and 0.5, 1, 1.5, 2, 3, 4, 5, 6, 8, 10 and 12 h after injection
Method of measurement
From drug serum concentration-time curve

2

Description
Time to reach maximum absolute neutrophil count
Timepoint
Before and at 4, 8, 10, 12, 16, 24, 36, 48, 72, and 96 h post-injection
Method of measurement
From absolute neutrophilcount-time curve

Intervention groups

1

Description
Intervention group: SC injection of a single dose of 300 mcg of Tinagrast produced by AryaTinaGene Biopharmaceutical Co. to healthy volunteers
Category
Treatment - Drugs

2

Description
Intervention group: SC injection of a single dose of 300 mcg of Neupogen produced by Amgen Inc to healthy volunteers
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dialysis Center, S. Motahhari Hospital
Full name of responsible person
Yahya Naserifard
Street address
Taleghani Street
City
Gonbade Kavous
Province
Golestan
Postal code
4916817693
Phone
+98 17 3252 5972
Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
AryaTinaGene Biopharmaceutical Co
Full name of responsible person
Majid Shahbazi
Street address
Aqqala Industrial Estate
City
Gorgan
Province
Golestan
Postal code
4931171756
Phone
+98 17 3453 3545
Fax
+98 17 3453 3554
Email
info@atgbio.com
Web page address
http://atgbio.com/home
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
AryaTinaGene Biopharmaceutical Co
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Sari Road, Km 2
City
Gorgan
Province
Golestan
Postal code
4916817693
Phone
+98 17 3252 5972
Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Sari Road, Km 2
City
Gorgan
Province
Golestan
Postal code
4916817693
Phone
+98 17 3252 5972
Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Gorgan University of Medical Sciences
Full name of responsible person
Hossein Amini
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Medical Pharmacy
Street address
Sari Road, Km 2
City
Gorgan
Province
Golestan
Postal code
4916817693
Phone
+98 17 3252 5972
Fax
+98 17 3252 5972
Email
haminhplc@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
Data are confidential and need permission from the company
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available