

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 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. Motahari 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 neutrophil count-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**

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Full name of responsible person

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+98 17 3252 5972

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haminhplc@yahoo.com

Person responsible for updating data**Contact****Name of organization / entity**

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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