Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Study of the pharmacokinetic and pharmacodynamic and safety properties of Tinapeg® (6 mg/0.6 ml syringes, AryaTinaGene Biopharmaceutical Co) in comparison to Neulastim® (6 mg/0.6 ml syringes, Amgen) in healthy volunteers

Protocol summary

Study aim

This study is designed to compare the pharmacokinetic and pharmacodynamic of Tinapeg® and Neulastim® in healthy volunteers.

Design

This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacodynamic and pharmacokinetic of Tinapeg and Neulastim in 24 healthy adults male volunteers. Volunteers will be sorted and receive a number from 1 to 24. In the first phase of the study, 12 volunteers will receive Tinapeg® produced by AryaTinaGene Biopharmaceutical Co. and the remaining 12 volunteers will receive Neulastim® produced by Amgen Inc. The administered drugs will be replaced by each other in the second phase of the study. Since in this study, the volunteers will receive both Test and Reference drugs, each volunteer will act as his own control.

Settings and conduct

The dose injection and subsequent sample collection will be performed in S. Motahhari hospital.

Participants/Inclusion and exclusion 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 the present study. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.

Intervention groups

A single subcutaneous 6 mg dose of Tinapeg® produced by AryaTinaGene Biopharmaceutical Co. and a 6 mg dose of Neulastim® produced by Amgen Inc in a cross-over design.

Main outcome variables

1. Pharmacokinetic: Plasma concentration; Area under plasma 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: **IRCT20130626013776N8**
Registration date: **2018-09-26, 1397/07/04**
Registration timing: **retrospective**

Last update: **2018-09-26, 1397/07/04**
Update count: **0**

Registration date

2018-09-26, 1397/07/04

Registrant information

Name
Hossein Amini
Name of organization / entity
Golestan University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2018-08-22, 1397/05/31
Expected recruitment end date
2018-09-22, 1397/06/31
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 Tinapeg® (6 mg/0.6 ml syringes, AryaTinaGene Biopharmaceutical Co) in comparison to Neulastim® (6 mg/0.6 ml syringes, Amgen) in healthy volunteers

Public title
Bioequivalence Study of Pegfilgrastim 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 signed 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 pegfilgrastim. 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 the present study. Receipt of any drug as part of a research study within 30 days prior to the present study. Donation or significant loss of whole blood (480 ml or more) within 30 days prior to the present study.
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
According to the crossover design of the study, the twenty four participants randimized into two sequences of Tinapeg-Neulastim and Neulastim-Tinapeg using command of rand in the Excel program.
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
2018-07-29, 1397/05/07
Ethics committee reference number
IR.GOUMS.REC.1397.090

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 pegfilgrastim
Timepoint
Before and 4, 8, 12, 16 (day 1), 24, 36 (day 2), 48, 60 (day 3) and 72 (day 4) and 96 h (day 5) after injection.
Method of measurement
ELISA method with special kit

2

Description

Absolute neutrophil count

Timepoint

Before the study drug injection and at 4, 8, 12, 16 (day 1), 24, 36 (day 2), 48, 60 (day 3), 72, 84 (day 4), 96 (day 5), 144 (day 7), 192 (day 9), 240 (day 11), and 312 (day 14) h post-injection.

Method of measurement

Cell counter

Secondary outcomes

1

Description

Time to reach maximum serum concentration

Timepoint

Before and 4, 8, 12, 16 (day 1), 24, 36 (day 2), 48, 60 (day 3) and 72 (day 4) and 96 h (day 5) after injection.

Method of measurement

From drug serum concentration-time curve

2

Description

Time to reach maximum absolute neutrophil count

Timepoint

Before the study drug injection and at 4, 8, 12, 16 (day 1), 24, 36 (day 2), 48, 60 (day 3), 72, 84 (day 4), 96 (day 5), 144 (day 7), 192 (day 9), 240 (day 11), and 312 (day 14) h post-injection.

Method of measurement

From absolute neutrophil count-time curve

Intervention groups

1

Description

Intervention group: A subcutaneous injection of a single dose of 6 mg of Tinapeg produced by AryaTinaGene Biopharmaceutical Co. to healthy volunteers

Category

Treatment - Drugs

2

Description

Intervention group: A subcutaneous injection of a single dose of 6 mg of Neulastim 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

Gonbade Kavous

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Taleghani Street

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haminhplc@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AryaTinaGene Biopharmaceutical Co

Full name of responsible person

Dr. Majid Shahbazi

Street address

Aqqala Industrial Estate

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Gorgan

Province

Golestan

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4931171756

Phone

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Fax

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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
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Person responsible for updating data

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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