

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 Jul 2026

Study of the pharmacokinetic and pharmacodynamic and safety properties of Somatin® (5 mg/1.5 ml cartridges, AryaTinaGene Biopharmaceutical Co) in comparison to Norditropin® (5 mg/1.5 ml cartridges, Novo Nordisk) in healthy volunteers

Protocol summary

Study aim

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

Design

This randomized, single-dose, two-way, crossover study is conducted to compare the pharmacodynamic and pharmacokinetic of Somatin® and Norditropin® in 30 healthy adults volunteers. Volunteers will be sorted and receive a number from 1 to 30. In the first phase of the study, 15 volunteers will receive Somatin® produced by AryaTinaGene Biopharmaceutical Co. and the remaining 15 volunteers will receive Norditropin® produced by Novo Nordisk Co. The administered drugs will be replaced by each other in the second phase of the study.

Settings and conduct

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

Participants/Inclusion and exclusion criteria

Volunteers, 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. 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.

Intervention groups

First intervention group: a single subcutaneous injection of Somatin (5 mg) manufactured by AryaTinaGene Biopharmaceutical Co. to 15 subjects. Second intervention group: A single subcutaneous injection of Norditropin (5 mg) manufactured by Novo Nordisk Co. to 15 subjects. Since in this study, the volunteers will receive both Test and Reference drugs, each volunteer

will act as his own control.

Main outcome variables

Drug serum concentration; area under the serum concentration-time curve

General information

Reason for update

The English title was not revised

Acronym

IRCT registration information

IRCT registration number: **IRCT20130626013776N20**

Registration date: **2020-03-28, 1399/01/09**

Registration timing: **prospective**

Last update: **2020-06-08, 1399/03/19**

Update count: **1**

Registration date

2020-03-28, 1399/01/09

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

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01
Expected recruitment end date
 2020-06-21, 1399/04/01
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 Somatin® (5 mg/1.5 ml cartridges, AryaTinaGene Biopharmaceutical Co) in comparison to Norditropin® (5 mg/1.5 ml cartridges, Novo Nordisk) in healthy volunteers

Public title
 Bioequivalence Study of Somatropin in Healthy Human Volunteers

Purpose
 Basic science

Inclusion/Exclusion criteria
Inclusion criteria:
 Volunteers, 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 somatropin. 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 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
 Both

Phase
 Bioequivalence

Groups that have been masked
 No information

Sample size
 Target sample size: **30**
 More than 1 sample in each individual
 Number of samples in each individual: **16**
 A volume of 2 ml of blood is obtained in each sampling time through a venous cannula

Randomization (investigator's opinion)
 Randomized

Randomization description
 Each subject is identified by a number from 1 to 30. This number is allocated according to their entrance to volunteers' list in the screening day. Then, the following randomization table is used according to the crossover design of the study. All participants randomized into two sequences of Test/Reference and Reference/Test products
 Subjects Dosing Sequence Day 1 Day 8
 1 R/T Reference Test 2 T/R Test Reference 3 T/R Test Reference 4 R/T Reference Test 5 T/R Test Reference 6 R/T Reference Test 7 R/T Reference Test 8 T/R Test Reference 9 T/R Test Reference 10 T/R Test Reference 11 R/T Reference Test 12 R/T Reference Test 13 T/R Test Reference 14 T/R Test Reference 15 T/R Test Reference 16 R/T Reference Test 17 T/R Test Reference 18 R/T Reference Test 19 R/T Reference Test 20 R/T Reference Test 21 T/R Test Reference 22 T/R Test Reference 23 R/T Reference Test 24 R/T Reference Test 25 R/T Reference Test 26 R/T Reference Test 27 T/R Test Reference 28 T/R Test Reference 29 T/T Test Reference 30 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
 Falsafi Building, Sari Road Km 2
City
 Gorgan
Province
 Golestan
Postal code
 4934174515

Approval date
 2020-03-09, 1398/12/19
Ethics committee reference number
 IR.GOUMS.REC.1398.352

Health conditions studied

1

Description of health condition studied

ICD-10 code
ICD-10 code description

Primary outcomes

1

Description

Serum concentration of somatropin, IGF-1 and IGFBP-3

Timepoint

–1.0, –0.5, 0, 1, 2, 3, 4, 6, 8, 10, 12, 16, 24, 48, 72 and 96 hours after injection

Method of measurement

Blood sampling and measurement of serum concentrations by chemiluminescence immunoassay

2

Description

Area under serum concentration-time curve

Timepoint

–1.0, –0.5, 0, 1, 2, 3, 4, 6, 8, 10, 12, 16, 24, 48, 72 and 96 hours after injection

Method of measurement

Blood sampling and measurement of serum concentrations by chemiluminescence immunoassay

Secondary outcomes

1

Description

Time to reach maximum serum concentration

Timepoint

Sampling at times of 1, 2, 3, 4 and 6 hours after injection

Method of measurement

From serum concentration-time curve

2

Description

Serum half-life

Timepoint

From the terminal 84 hours of serum concentration-time profile

Method of measurement

Blood sampling and measurement of serum concentrations by chemiluminescence immunoassay

Intervention groups

1

Description

Intervention group: A subcutaneous injection of a single dose of 5 mg of Somatin produced by AryaTinaGene Biopharmaceutical Co. to healthy volunteers

Category

Treatment - Drugs

2

Description

Intervention group: A subcutaneous injection of a single dose of 5 mg of Norditropin produced by Novo Nordisk Co. 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

Gorgan

Province

Golestan

Postal code

4916817693

Phone

+98 17 3252 5972

Fax

+98 17 3252 5972

Email

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

City

Gorgan

Province

Golestan

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4931171756

Phone

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Email

info@atgbio.com

Web page address

<http://atgbio.com/home>

Grant name

AryaTinaGene Biopharmaceutical Co

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**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

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available