Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

A randomized, two-armed, double-blind, single-dose, crossover, two sequence, active-controlled, multi-center, bioequivalence clinical trial to compare PK parameters and safety of Factor VIII, recombinant human with Fc fusion (rFVIII-Fc) (Coageight, produced by AryoGen Pharmed Company (versus rFVIII-Fc (Elocta®, produced by Sobi Company) in previously treated patients with severe hemophilia A

Protocol summary

Study aim
compare rFVIII-Fc (Coageight, produced by AryoGen Pharmed Co.) with rFVIII-Fc (Elocta¬®, produced by Sobi Co.) by dose-normalized area under the curve (dnAUC last)

Design
The study is designed as a randomized, two armed, double-blind, single-dose, crossover, two sequence, active-controlled, multi-center, bioequivalence clinical trial with primary endpoint of dose-normalized area under the curve (dnAUC last)- 50 patients, Two arm parallel group randomised trial with blinded postoperative care and outcome assessment

Settings and conduct
One-Stage Assay (OSA) and Chromogenic Substrate Assay (CSA)

Participants/Inclusion and exclusion criteria
Investigators assess the inclusion/exclusion criteria in patients, get ICF, randomized, Enrollment

Intervention groups
rFVIII-Fc (Aryogen Pharmed Co.), IV, 50 units/kg, Single dose, then rFVIII-Fc (Elocta®, Sobi Co.), Cross-over

Main outcome variables
dnAUC last; dose; normalized area under the curve 12 days after the first intervention; One-Stage Assay (OSA) and Chromogenic Substrate Assay (CSA)

General information

Reason for update
Trial Completed

Acronym
FAC

IRCT registration information
IRCT registration number: **IRCT20150303021315N31**
Registration date: **2023-05-04, 1402/02/14**
Registration timing: **prospective**

Last update: **2023-10-25, 1402/08/03**
Update count: **1**

Registration date
2023-05-04, 1402/02/14

Registrant information

Name
Nassim Anjidani

Name of organization / entity
Orchid Pharmed

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-07-26, 1402/05/04

Expected recruitment end date
2024-02-04, 1402/11/15

Actual recruitment start date
2023-06-22, 1402/04/01

Actual recruitment end date
2023-09-27, 1402/07/05

Trial completion date

2023-09-27, 1402/07/05

Scientific title

A randomized, two-armed, double-blind, single-dose, crossover, two sequence, active-controlled, multi-center, bioequivalence clinical trial to compare PK parameters and safety of Factor VIII, recombinant human with Fc fusion (rFVIII-Fc) (Coageight, produced by AryoGen Pharmed Company (versus rFVIII-Fc (Elocta®, produced by Sobi Company) in previously treated patients with severe hemophilia A

Public title

Bioequivalence clinical trial to compare PK parameters and safety of Factor VIII, recombinant human with Fc fusion (rFVIII-Fc) (Coageight, produced by AryoGen Pharmed Company) versus Elocta® in previously treated patients with severe hemophilia A

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Male patients ≥ 12 years, with signed informed consent by the patient, or the patient's legally authorized representative for patients under the legal age Diagnosed with severe hemophilia A (endogenous FVIII <1% [1 IU/dL]) History of at least 150 documented prior exposure days to any FVIII product Having adequate bone marrow and organ function:• Plt ≥ 80,000 cells/µL • Hgb ≥ 8 mg/dL• eGFR ≥ 30 mL/min• ALT or AST ≤ 5×ULN• Serum bilirubin ≤ 1.5×ULN

Exclusion criteria:

Measurable anti-drug antibody activity against FVIII (≥ 0.6 BU/mL) at screening or a history of developing anti FVIII antibody History of other coagulation disorders except for hemophilia A Acute hemorrhagic state Infection with HCV or HBV HIV-positive patients Infusion of any products containing FVIII within 7 days prior to first administration Previous treatment with commercially available extended half-life products Receiving drugs which increase bleeding tendency (e.g: Anti-coagulants, antiplatelets, omega 3, Vit E, etc.) within 2 weeks of screening. NSAIDs are permitted. Current systemic treatment with immunosuppressive drugs Hypersensitivity or anaphylaxis associated with any FVIII concentrate or intravenous immunoglobulin (IVIg) Planned elective surgery Current enrolment or willing to enroll in any other experimental study during the time of current trial Subjects assessed by the investigator to be unable or unwilling to comply with the requirements of the protocol (e.g.: physical, psychological and mental problems)

Age

From **12 years** old

Gender

Male

Phase

Bioequivalence

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

The randomization plan of the patients will be carried out centrally using an R-CRAN software version 4.0.3 with the size 2 or 4 blocks. for a total of 50 patients, randomization scheme will be implemented crosses-over with sequence AB or BA. Once the randomization has been made, each patient is given a code with which he will be identified throughout the study. The assigned code will be made up of 3 numbers (corresponding to the randomization number) and by 4 initials (corresponding to the 2 first letters of the first name, the 2 first letters of the first surname), and 3 numbers (center code), for example ABCD001FAC-001. The randomization number will be assigned in a consecutive way.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, subjects and the product administrators are blinded. The size of vials is different. For this purpose, subjects and administrator of the drug will be blinded by considering two nurses in each center: one nurse who opens the drug package and prepares the drug for injection, and another nurse who injects the drugs and will remain blind throughout the study.

Placebo

Not used

Assignment

Crossover

Other design features

Single-dose- two sequence

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research ethics committees of Iran university of medical sciences

Street address

Iran University of Medical Sciences Shahid Hemmat Highway Tehran 14496-14535, IRAN

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-04-19, 1402/01/30

Ethics committee reference number

IR.IUMSREC.1402.034

Health conditions studied

1

Description of health condition studied
Severe hemophilia A
ICD-10 code
Z14.02
ICD-10 code description
Symptomatic hemophilia A carrier

Primary outcomes

1

Description
dnAUC last (dose-normalized area under the curve)
Timepoint
12 days after the first intervention
Method of measurement
One-Stage Assay (OSA) and Chromogenic Substrate Assay (CSA)

Secondary outcomes

1

Description
AUC inf
Timepoint
pre-dose and 0.25, 0.5, 1, 3, 6, 8, 24, 48, 72, 96 and 120 h after each infusion
Method of measurement
One-Stage Assay (OSA) and Chromogenic Substrate Assay (CSA)

2

Description
Cmax
Timepoint
pre-dose and 0.25, 0.5, 1, 3, 6, 8, 24, 48, 72, 96 and 120 h after each infusion
Method of measurement
One-Stage Assay (OSA) and Chromogenic Substrate Assay (CSA)

3

Description
Incremental recovery (IR)
Timepoint
pre-dose and 0.25, 0.5, 1, 3, 6, 8, 24, 48, 72, 96 and 120 h after each infusion
Method of measurement
One-Stage Assay (OSA) and Chromogenic Substrate Assay (CSA)

4

Description
Half-life (T ½)
Timepoint
pre-dose and 0.25, 0.5, 1, 3, 6, 8, 24, 48, 72, 96 and 120 h after each infusion
Method of measurement
One-Stage Assay (OSA) and Chromogenic Substrate Assay (CSA)

5

Description
Vd
Timepoint
pre-dose and 0.25, 0.5, 1, 3, 6, 8, 24, 48, 72, 96 and 120 h after each infusion
Method of measurement
One-Stage Assay (OSA) and Chromogenic Substrate Assay (CSA)

6

Description
Clearance
Timepoint
pre-dose and 0.25, 0.5, 1, 3, 6, 8, 24, 48, 72, 96 and 120 h after each infusion
Method of measurement
One-Stage Assay (OSA) and Chromogenic Substrate Assay (CSA)

7

Description
Assessment of Adverse events
Timepoint
At screening and on days 0,1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12 and 28
Method of measurement
Clinical monitoring

8

Description
Immunogenicity: Anti-drug antibody
Timepoint
At screening and on days 7, 12 and 28
Method of measurement
Nijmegen Bethesda assay

Intervention groups

1

Description
Intervention group: rFVIII-Fc (Aryogen Pharmed Co.), IV, 50 units/kg, Single dose, then rFVIII-Fc (Elocta®, Sobi Co.), Cross-over
Category
Treatment - Drugs

2

Description
Intervention group: rFVIII-Fc (Elocta®, Sobi Co.), IV, 50 units/kg, Single dose, then rFVIII-Fc (Aryogen Pharmed Co.), Cross-over

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Khomeini Hospital
Full name of responsible person
Dr. Katayoun Karimi
Street address
Imam Khomeini Hospital Complex, Tohid Squre, Tehran, Iran
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Postal code
1419733141
Phone
+98 21 6119 0000
Email
Dr_k_karimi_52071@yahoo.com

2

Recruitment center
Name of recruitment center
Mofid Children's Hospital
Full name of responsible person
Dr Samin Alavi Bajestani
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Mofid Children's Hospital, Shariati Street, Tehran, Iran
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3

Recruitment center
Name of recruitment center
Shahid Dastgheib Hospital
Full name of responsible person
Dr Mohammad Reza Bordbar- Dr Asqar Bazrafshan
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Hafez Hospital, Shahid Chamran Blvd., Hafez Hospital, Shiraz, Iran
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4

Recruitment center
Name of recruitment center
Seyed Shohada Hospital
Full name of responsible person
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5

Recruitment center
Name of recruitment center
Sarvar Clinic
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
AryoGen Company
Full name of responsible person
Mohammad Saffarioun - Chief Executive Officer - AryoGen

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No. 140, 24th Km Tehran-Karaj Makhsous road, Alborz, Iran
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3164819712
Phone
+98 26 3610 6480
Email
contact@aryogen.com
Web page address

Grant name

Grant code / Reference number

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

Title of funding source
AryoGen Company

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
Orchid Pharmed Co.
Full name of responsible person
Dr. Nasim Anjidani
Position
Medical Department Manager
Latest degree
Specialist
Other areas of specialty/work
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Latest degree
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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