

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

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##### Email address

amini@orchidpharmed.com

#### 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  $\geq 12$  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  $\geq 80,000$  cells/ $\mu\text{L}$  • Hgb  $\geq 8$  mg/dL • eGFR  $\geq 30$  mL/min • ALT or AST  $\leq 5 \times \text{ULN}$  • Serum bilirubin  $\leq 1.5 \times \text{ULN}$

#### Exclusion criteria:

Measurable anti-drug antibody activity against FVIII ( $\geq 0.6$  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

## 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

C<sub>max</sub>

#### 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<sub>½</sub>)

#### 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

V<sub>d</sub>

#### 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 Squire, Tehran, Iran

##### City

Tehran

##### Province

Tehran

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##### Phone

+98 21 6119 0000

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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

##### Street address

Mofid Children's Hospital, Shariati Street, Tehran, Iran

##### City

Tehran

##### Province

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##### Postal code

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##### Phone

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##### Email

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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

##### Street address

Hafez Hospital, Shahid Chamran Blvd., Hafez Hospital, Shiraz, Iran

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##### Province

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### 4

#### Recruitment center

##### Name of recruitment center

Seyed Shohada Hospital

##### Full name of responsible person

Dr Majid Qanavat

##### Street address

Seyed-al-Shohada Hospital, Farshadi Alley, Khayam St., Isfahan, Iran

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Isfahan

##### Province

Isfahan

##### Postal code

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##### Phone

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##### Email

ghanavatmajid@yahoo.com

### 5

#### Recruitment center

##### Name of recruitment center

Sarvar Clinic

##### Full name of responsible person

Dr Zahra Badiiee

##### Street address

No. 8, Sarvar Clinic, 17 Shahrivar Street ,Mashhad, Khorasan

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##### Province

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##### Postal code

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##### Phone

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##### Email

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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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**Province**

Alborz

**Postal code**

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**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**

Medical Pharmacy

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Dr Aziz Eghbali

**Position**

Associated Professor Iran University of medical sciences Aliasghar medical education hospital .Tehra

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Hematology

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Ali-Asghar Children's Hospital, Shahid Vahid Dastgerdi Street, Moddares Highway, Tehran, Iran

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

Orchid Pharmed Co.

**Full name of responsible person**

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**Position**

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**Other areas of specialty/work**

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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