

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

Efficacy analysis of Recombinant factor VIIa (Aryogen) in Comparison with Novoseven® on patients with congenital hemophilia A/B with inhibitors

Protocol summary

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Summary

The objective of this randomized, double blind trial is to compare the efficacy of Novoseven® and Recombinant factor VIIa (Aryogen) on the patients with congenital hemophilia A/B with inhibitors,. In this study, 66 patients with congenital hemophilia A/B with inhibitors who meet the inclusion/exclusion criteria will be recruited and randomly assigned into two interventions or a control group. The patients in the intervention group will receive Recombinant factor VIIa (Aryogen) and in the control group will receive Novoseven®. Pain relief, improvement in joint mobility, serum level of factor VIIa (FVII:C) will be measured before and after the intervention and compared between the groups.

Recruitment status

Recruitment complete

Funding source

Aryogen Pharmaceutical company

Expected recruitment start date

2012-02-19, 1390/11/30

Expected recruitment end date

2012-04-29, 1391/02/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201202106302N2**

Registration date: **2012-03-03, 1390/12/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-03-03, 1390/12/13

Registrant information

Name

Kamran Kamyar

Name of organization / entity

AryoGen Biopharma Company

Country

Iran (Islamic Republic of)

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Email address

Scientific title

Efficacy analysis of Recombinant factor VIIa (Aryogen) in Comparison with Novoseven® on patients with congenital hemophilia A/B with inhibitors

Public title

Efficacy analysis of Recombinant factor VIIa (Aryogen) in Comparison with Novoseven® on patients with congenital hemophilia A/B with inhibitors

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: known case of congenital hemophilia A/B with inhibitors level more than 5 Bethesda unit, age older than 2 , gender male or female, proper IV line for drug injection, the severity of bleeding should be evaluable Exclusion criteria: Presence of any congenital or acquired coagulopathy disorders except for congenital hemophilia A/B with inhibitors such as:(liver disease (hepatitis), uremia, malignancy, vitamin K deficiency) , severe atherosclerotic disease, any local pathology that predisposes the patient to bleeding, having been under immune tolerance induction therapy during one month prior to the study, Platelet count lower than 50000

Age

From **2 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iranian blood transfusion organization

Street address

IBTO bldg, Hemmat Exp.Way, Next to the Milad Tower, Tehran, Iran

City

tehran

Postal code

14665-1157

Approval date

2011-05-02, 1390/02/12

Ethics committee reference number

395/ب

Health conditions studied

1

Description of health condition studied

congenital hemophilia A/B with inhibitors

ICD-10 code

D66, D67

ICD-10 code description

Hereditary factor VIII deficiency, Hereditary factor IX deficiency

Primary outcomes

1

Description

Pain intensity

Timepoint

1,3,6,9 hours after first injection(according to Kavakli global response scoring system)

Method of measurement

clinically,by the hematologist(according to Kavakli global response scoring system)

2

Description

joint mobility

Timepoint

1,3,6,9 hours after first injection(according to Kavakli global response scoring system)

Method of measurement

clinically,by the hematologist detection (according to Kavakli global response scoring system)

Secondary outcomes

1

Description

serum level of factor VIIa (FVII:C)

Timepoint

in time zero(immediately befor injection) and 20 minutes after first injection

Method of measurement

by ELISA labratory test

2

Description

Amplitude of probable side effects

Timepoint

during therapy and monthly until 3 months after therapy

Method of measurement

clinically, by the hematologist

Intervention groups

1

Description

in interventional group recombinant factor VIIa (Aryogen) is injected to patients at below style:90μ g/kg as start dose then 120μ g/kg every 2 hours for 3 dose

Category

Treatment - Drugs

2

Description

in control group Novoseven® is injected to patients at below style: 90μ g/kg as start dose then 120μ g/kg every 2 hours for 3 dose

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Blood Transfusion Organization

Full name of responsible person

Dr. Mohammad Faranoush

Street address

IBTO bldg, Hemmat Exp.Way, Next to the Milad Tower, Tehran, Iran

City

tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

AryoGen Biopharma Company

Full name of responsible person

Dr. Behrouz Vaziri, general manager

Street address

Cross Tajbakhsh Street, 24th Kilometer Makhsoos, Tehran - Iran . AryoGen Biopharma Co

City

Garmdareh

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

AryoGen Biopharma Company

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact

Name of organization / entity

AryoGen Biopharma Company

Full name of responsible person

Dr. Kamran Kamyar

Position

General Practitioner/ Medical Manager

Other areas of specialty/work**Street address**

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Mohammad Faranoush

Position

Pediatric Hematologist Oncologist Associate Professor

Other areas of specialty/work**Street address**

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Full name of responsible person

Dr. Kamran Kamyar

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General Practitioner/ Medical Manager

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty