Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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

Protocol summary

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.

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)

Phone

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Email address

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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

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 tranfusion 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 Makhsous, 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

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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

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Person responsible for updating data

Contact

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Other areas of specialty/work

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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