Clinical Trial Protocol
Iranian Registry of Clinical Trials

29 Jun 2026

Efficacy analysis of Recombinant factor VIIa (Aryogen) in Comparison with Novoseven® on patients with congenital FVII deficiency

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 FVII deficiency. In this study, 66 patients with congenital FVII deficiency 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®.serum level of factor VIIa (FVII:C), frequency and severity of bleeding episodes will be measured before and after the intervention and compared between the groups

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201104266302N1**
Registration date: **2011-05-23, 1390/03/02**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2011-05-23, 1390/03/02

Registrant information

Name

Kamran Kamyar

Name of organization / entity

AryoGen Biopharma Company

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

AryoGen Biopharma Company

Expected recruitment start date

2012-02-07, 1390/11/18

Expected recruitment end date

2012-05-09, 1391/02/20

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 FVII deficiency

Public title

The comparison of efficacy between Novoseven® and Recombinant factor VIIa (Aryogen)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:known case of congenital FVII deficiency that frequency of his/her bleeding episodes more than one per month,age older than 2,gender: male or female,proper IV line for drug injection,Exclusion criteria: Presence of any congenital or acquired coagulopathy disorders except for congenital F VII deficiency, liver disease (hepatitis), uremia, malignancy, vitamin K deficiency, having received Novoseven® as prophylactic therapy in congenital FVII deficiency since one month ago,severe atherosclerotic disease,any local pathology that predisposes the patient to bleeding, presence of antibody against FVII,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

394/ب

Health conditions studied

1

Description of health condition studied

congenital FVII deficiency

ICD-10 code

D68.2

ICD-10 code description

Hereditary deficiency of other clotting factors

Primary outcomes

1

Description

serum level of factor VIIa (FVII:C)

Timepoint

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

Method of measurement

by ELISA labratory test

Secondary outcomes

1

Description

frequency of bleeding episodes

Timepoint

initially and one month after starting prophylactic therapy

Method of measurement

clinically,by the hematologist detection

2

Description

Amplitude of probable side effects

Timepoint

Weekly 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:30µ g/kg once per week for one month as prophylactic therapy

Category

Treatment - Drugs

2

Description

in control group Novoseven® is injected to patients at below style:30µ g/kg once per week for one month as prophylactic therapy

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iranian Blood Transfusion Organization

Full name of responsible person

Dr. Mohammad Faranoush,Professor of Pediatric Hematology & Oncology

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Sponsors / Funding sources

1

Sponsor
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AryoGen Biopharma Company
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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

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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