

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

kamyark@aryogen.com

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

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

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)

Phone

00982616102587.00982616101568

Email address

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

Street address

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

City

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

Tehran

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

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

City

Tehran

Postal code

3164819711

Phone

00982616101568-72 ,00982616102587

Fax

+98 26 1610 4644

Email

Email:kamyark@aryogen.com

Web page address

www.aryogen.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iranian Blood Transfusion Organization

Full name of responsible person

Dr. Mohammad Faranoush

Position

Pediatric Hematologist Oncologist Associate Professor

Other areas of specialty/work

Street address

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

City

Tehran

Postal code

14665-1157

Phone

+98 218860150130

Fax

+98 21 8860 1555

Email

Email:faranoush47@gmail.com

Web page address

http://www.ibto.ir

Person responsible for updating data

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

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

City

Tehran

Postal code

3164819711

Phone

00982616101568-72 ,00982616102587

Fax

+98 26 1610 4644

Email

Email:kamyark@aryogen.com

Web page address

www.aryogen.com

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