Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

Prospective,open-label,uncontrolled,phase III study to assess the efficacy, safety and pharmacokinetics of Octafibrin for on-demand treatment of acute bleeding and to prevent bleeding during and after surgery in paediatric subjects with congenital fibrinogen deficiency

Protocol summary

Summary

Goal:To demonstrate the efficacy and safety of Octafibrin for on-demand treatment of acute bleeding episodes (spontaneous or after trauma) . Study design:multinational, multicentre. prospective,open-label,uncontrolled,Phase III study. Number of subjects:3 subjects between 6-12 years old with congenital afibrinogenemia Inclusion: age 6-12; documented diagnosis of congenital fibrinogen deficiency; Historical plasma fibrinogen activity of <50ml/dl; expected to have an acute bleeding episode(spontaneous or after trauma) or planing to undergo elective surgery; Informed consent signed by the subject's legal guardian Exclusion: Life expectancy<6 months; bleeding disorder other than congenital fibrinogen dificiency; prophylactic treatment with a fibrinogen concentrate; any fibrinogen concentrate or other fibrinogen-containing blood product within 2 weeks prior to start of treatment for the PK phase,a bleeding episode, or surgery; any coagulation drug within 1 week prior to start of PK phase or treatment for the bleeding episode or surgery, or as a planned or expected medication during the time period from Day 1 until 24 hours presence or history of hypersensitivity to study medication,DVT or pulmonary embolism, arterial thrombosis within 1 year prior to start drug infusion,hypersensitivity to human plasma protein,Oesophageal varicose bleeding intervention: infusion of Octafibrin and monitoring Duration:30 days after infusion primary endpoint:the overall clinical assessment of the haemostatic efficacy of octafibrin in treating the first documented bleeding episode of each patient

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112320051N3**
Registration date: **2015-09-01, 1394/06/10**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2015-09-01, 1394/06/10

Registrant information

Name
Mehran Karimi
Name of organization / entity
Hematology Research Center, Shiraz University of Medical Sciences
Country
Iran (Islamic Republic of)
Phone
+98 71 3612 5617
Email address
karimim@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Octapharma AG

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2015-12-22, 1394/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Prospective,open-label,uncontrolled,phase III study to assess the efficacy, safety and pharmacokinetics of Octafibrin for on-demand treatment of acute bleeding and to prevent bleeding during and after surgery in paediatric subjects with congenital fibrinogen deficiency

Public title
The effect of haemostatic factor,Octafibrin in congenital afibrinogenemia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion: age 6-12; documented diagnosis of congenital fibrinogen deficiency; Historical plasma fibrinogen activity of <50ml/dl; expected to have an acute bleeding episode(spontaneous or after trauma) or planing to undergo elective surgery; Informed consent signed by the subject's legal guardian Exclusion: Life expectancy<6 months; bleeding disorder other than congenital fibrinogen dificiency; prophylactic treatment with a fibrinogen concentrate; any fibrinogen concentrate or other fibrinogen-containing blood product within 2 weeks prior to start of treatment for the PK phase,a bleeding episode, or surgery; any coagulation drug within 1 week prior to start of PK phase or treatment for the bleeding episode or surgery, or as a planned or expected medication during the time period from Day 1 until 24 hourspresence or history of hypersensitivity to study medication,DVT or pulmonary embolism, arterial thrombosis within 1 year prior to start drug infusion,hypersensitivity to human plasma protein,Oesophageal varicose bleeding
Age
From **6 years** old to **12 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **3**
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

1

Registry name
EudraCT
Secondary trial Id
2014-005115-16
Registration date
2017-11-21, 1396/08/30

Ethics committees

1

Ethics committee
Name of ethics committee
Ethic Committee of Shiraz University of Medical Sciences
Street address
Next to Helal Ahmar-Zand Avenue-Shiraz
City
Shiraz
Postal code
Approval date
2015-08-05, 1394/05/14
Ethics committee reference number
IR.SUMS.REC.1394.76

Health conditions studied

1

Description of health condition studied
Congenital Afibrinogenemia
ICD-10 code
D68.2
ICD-10 code description
Hereditary deficiency of other clotting factors

Primary outcomes

1

Description
overall clinical assessment of the haemostatic efficacy of Octafibrin
Timepoint
24 hours
Method of measurement
4-point haemostatic efficacy scale

Secondary outcomes

1

Description
‘clot strength’ or ‘clot firmness’
Timepoint
1 hour
Method of measurement
blood sampling

Intervention groups

1

Description

Infusion of Octafibrin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyedo Shohada Isfahan Hospital

Full name of responsible person

Dr. Mehran Karimi

Street address

27, jahannema bldg, 10th alley

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Octapharma

Full name of responsible person

Bruce A. Schwartz

Street address

USA, Inc. | 121 River Street, Suite 1201 | Hoboken, New Jersey 07030 |

City

Hoboken

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Octapharma

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

Shiraz University of Medical Sciences, Hematology Research Center

Full name of responsible person

Mehran Karimi

Position

Sub-special in pediatrics hematology and oncology

Other areas of specialty/work

Street address

Mohammad Rasoolallah research Tower, Khalili Street

City

Shiraz

Postal code

Iran

Phone

+98 71 3628 1563

Fax

Email

karimim@sums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Mehran Karimi

Position

Professor of Pediatric Hematology-Oncology

Hematology Research Center

Other areas of specialty/work

Street address

Hematology Research Center, Nemazee Hospital, Zand street, Shiraz

City

Shiraz

Postal code

Phone

00

Fax

Email

karimim@sums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shiraz university of Medical Sciences, Hematology Research Center

Full name of responsible person

Zohreh Zahedi

Position

BS, Research

Other areas of specialty/work

Street address

Mohammad rasoollalah research Tower, Khalili Street

City

Shiraz

Postal code

Phone

00

Fax

Email

Web page address

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