

# 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 planning to undergo elective surgery; Informed consent signed by the subject's legal guardian. Exclusion: Life expectancy < 6 months; bleeding disorder other than congenital fibrinogen deficiency; 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 planning to undergo elective surgery; Informed consent signed by the subject's legal guardian  
Exclusion: Life expectancy < 6 months; bleeding disorder other than congenital fibrinogen deficiency; 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

**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

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## Person responsible for scientific inquiries

### Contact

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## 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  
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BS, Research  
**Other areas of specialty/work**  
**Street address**  
Mohammad rasoolallah research Tower, Khalili Street  
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Shiraz  
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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*