

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

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

### Protocol summary

#### Summary

Objectives: To demonstrate the efficacy and safety of Octafibrin for on-demand treatment of acute bleeding episodes and to prevent bleeding (spontaneous or after trauma) during and after surgery in subjects with congenital fibrinogen deficiency” Inclusion criteria: Aged  $\geq 12$  years ; Documented diagnosis of congenital fibrinogen deficiency, expected to require on-demand treatment for bleeding or surgical prophylaxis :Fibrinogen deficiency manifested as afibrinogenaemia or severe hypofibrinogenaemia; Expected to have an acute bleeding episode (spontaneous or after trauma) or planning to undergo elective surgery. Exclusion criteria: Life expectancy <6 months ;Other Congenital Bleeding disorders ; Prophylactic treatment with a fibrinogen concentrate ;Treatment with any fibrinogen concentrate or other fibrinogen-containing blood product within 2 weeks prior to start of treatment for the bleeding episode or surgery. Treatment with any coagulation-active drug (within 1 week prior to 24 hours after start of treatment Population: 2-4 patient more than 12 ages with congenital Afibrinogenemia Design:Prospective ; open-label, uncontrolled, Phase III Intervention: assessment of efficacy and safety of Octafibrin and till 30 days after injection Primary endpoint: The primary endpoint is the overall clinical assessment of the haemostatic efficacy of Octafibrinin treating the first documented bleeding episode of each patient

### General information

#### Acronym

#### IRCT registration information

IRCT registration number: **IRCT2014112420051N4**  
Registration date: **2015-09-24, 1394/07/02**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

#### Registration date

2015-09-24, 1394/07/02

#### 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 Company

#### Expected recruitment start date

2015-09-20, 1394/06/29

#### Expected recruitment end date

2015-12-20, 1394/09/29

#### 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 and safety of Octafibrin for on-demand treatment of acute bleeding and to prevent bleeding during and after surgery in subjects with

congenital fibrinogen deficiency”

**Public title**

The assessment of the efficacy and safety of Fibrinogen ( Octafibrin) in subjects with congenital fibrinogen deficiency”

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Aged  $\geq 12$  years ; Documented diagnosis of congenital fibrinogen deficiency, expected to require on-demand treatment for bleeding or surgical prophylaxis :Fibrinogen deficiency manifested as afibrinogenaemia or severe hypofibrinogenaemia; Expected to have an acute bleeding episode (spontaneous or after trauma) or planning to undergo elective surgery. Exclusion criteria: Life expectancy  $< 6$  months ;Other Congenital Bleeding disorders ; Prophylactic treatment with a fibrinogen concentrate ;Treatment with any fibrinogen concentrate or other fibrinogen-containing blood product within 2 weeks prior to start of treatment for the bleeding episode or surgery. Treatment with any coagulation-active drug (within 1 week prior to 24 hours after start of treatment

**Age**

From **12 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **24**

**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**

Efficacy and Safety Study of Octafibrin for On-demand Treatment of Acute Bleeding and Prevention Bleeding During and After Surgery

**Secondary trial Id**

NCT02267226

**Registration date**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Shiraz University of Medical Science

**Street address**

inside HELAL AHMAR Building; Zand Avenue

**City**

SHIRAZ

**Postal code****Approval date**

2015-08-02, 1394/05/11

**Ethics committee reference number**

IR.SUMS.REC.1394.76

**2****Ethics committee****Name of ethics committee**

Added at 2017-11-04: Ethics committee of Isfahan University of Medical Sciences

**Street address**

Added at 2017-11-04:

**City**

Added at 2017-11-04: Isfahan

**Postal code**

Added at 2017-11-04:

**Approval date**

2016-11-25, 1395/09/05

**Ethics committee reference number**

Added at 2017-11-04: p/12/4/M/277

**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**

the overall clinical assessment of the haemo-static efficacy of Octafibrin in treating the first documented bleeding episode of each patient

**Timepoint**

24 hrs after up to 30 days

**Method of measurement**

the assessment made by the investigator on the 4-point rating scale

**Secondary outcomes****1****Description**

Clot strength (MCF)

#### Timepoint

at pre infusion and at 1 hour after first infusion up to 30 days

#### Method of measurement

changes of MCF from pre infusion will be summarised using descriptive statistics and displayed graphically: a correlation analysis between haemostatic efficacy assessment

## Intervention groups

### 1

#### Description

the administration of Octafibrin for bleeding

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shiraz University of Medical Science

##### Full name of responsible person

MEHRAN KARIMI

##### Street address

##### City

SHIRAZ

### 2

#### Recruitment center

##### Name of recruitment center

Added at 2016-11-27: Seyed al shohada Hospital

##### Full name of responsible person

Added at 2016-11-27: Dr. Hamid Hoodfar

##### Street address

Added at 2016-11-27: Motahari st

##### City

Added at 2016-11-27: Isfahan

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Octapharma AG

##### Full name of responsible person

Flora Peyvandi

##### Street address

A. Bianchi Bonomi Hemophilia and Thrombosis Center, University of Milan, Department of Medicine and Medical Specialties, IRCCS Maggiore Hospital, Mangiagalli and Regina Elena Foundation, Via Pace 9 20122

##### City

Milan

##### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Octapharma AG

#### 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 Science

##### Full name of responsible person

MEHRAN KARIMI

##### Position

Professor of Pediatric Hematology-Oncology

##### Other areas of specialty/work

##### Street address

Pediatrics Department, Nemazee Hospital ;Nemazee Squer

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+98 71 3628 1563

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mkarimi820@gmail.com

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## 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

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## **Person responsible for updating data**

### **Contact**

**Name of organization / entity**

Heamatology Research Center ; Shiraz University of  
Medical Sciences

**Full name of responsible person**

Zohreh Zahedi

**Position**

Bs in Nursing

**Other areas of specialty/work**

**Street address**

Mohammad rasulallah Research Tower ;Khalili Street ;

**City**

Shiraz

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**Phone**

00

**Fax**

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zohrezahedi@gmail.com

**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*