Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 ≥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 ≥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

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Person responsible for scientific inquiries

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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

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Mohammad rasulallah Research Tower ;Khalili Street ;

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00

Fax

Email

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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