

# FIBCON: FIBrinogen CONcentrate in paediatric cardiopulmonary bypass

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|--|---|---|
| <b>Submission date</b><br>01/05/2014   | <b>Recruitment status</b><br>No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered<br><input type="checkbox"/> Protocol |
| <b>Registration date</b><br>01/05/2014 | <b>Overall study status</b><br>Completed          | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results |
| <b>Last Edited</b><br>14/11/2022       | <b>Condition category</b><br>Surgery              | <input type="checkbox"/> Individual participant data  |

## Plain English summary of protocol

### Background and study aims

Newborn babies and infants needing surgery for congenital heart disease suffer the most from bleeding within the chest. As a result, they are frequently exposed to many blood products, and may also suffer consequences of blood loss. We want to find out whether giving a new blood product, human fibrinogen concentrate, to these infants, will reduce bleeding and exposure to other blood products. A unique aspect of this study will be that study drug exposure and dose will be personalised to the patient on the basis of bleeding risk. Because bleeding risk cannot be estimated accurately before the operation, we will assess this during the operation using a test for coagulation, known as rotational thromboelastometry (ROTEM).

### Who can participate?

Babies who are aged less than 36 weeks with congenital heart disease requiring surgery.

### What does the study involve?

We will give the study drug to only those infants who are at higher risk of bleeding during the ROTEM screening during the operation. These infants will be randomly allocated to receive either fibrinogen or a placebo (dummy). Infants at lower risk will not be allocated to any group, but remain in the study, forming an observational group. All infants will receive standard care with respect to all other aspects.

### What are the possible benefits and risks of participating?

As this is an early phase trial, it is impossible to delineate risks or benefits in any meaningful way.

### Where is the study run from?

Evelina Childrens Hospital (UK)

### When is the study starting and how long is it expected to run for?

The study starts in June 2014 and ends in March 2016

### Who is funding the study?

CSL Behring (UK)

Who is the main contact?  
Dr Shane Tibby  
Shane.Tibby@gstt.nhs.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Shane Tibby

**Contact details**  
2nd floor, Evelina Childrens Hospital  
Westminster Bridge Road  
London  
United Kingdom  
SE1 7EH  
-  
Shane.Tibby@gstt.nhs.uk

## Additional identifiers

**EudraCT/CTIS number**  
2013-003532-68

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
16254

## Study information

**Scientific Title**  
Fibrinogen concentrate supplementation in the management of bleeding during paediatric cardiopulmonary bypass: a phase 1B/2A, open-label dose-escalation study

**Study objectives**  
Fibrinogen concentrate supplementation during paediatric cardiopulmonary bypass may decrease the incidence and severity of postoperative bleeding, and reduce the need for transfusion of blood and ancillary blood products (platelets, fresh frozen plasma, and cryoprecipitate). The primary objective of this trial is to determine the dose of intraoperative fibrinogen concentrate required to achieve physiological levels of fibrin polymerization of 8 to 13 mm as measured by the rotational thromboelastometry (ROTEM) measure of fibrin-based clotting: FibTEM MCF (equating to plasma fibrinogen concentrations of 1.5 to 2.5 g/L), immediately prior to separation from cardiopulmonary bypass in neonates and children < 12 kg.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

London - London Bridge Research Ethics Committee, 26/02/2014, ref: 14/LO/0267

**Study design**

Randomised; Interventional and Observational; Design type: Process of Care, Treatment, Cohort study

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

Other

**Study type(s)**

Treatment

**Participant information sheet**

Not available in web format, please use the contact details to request a patient information sheet

**Health condition(s) or problem(s) studied**

Topic: Children; Subtopic: All Diagnoses; Disease: All Diseases

**Interventions**

Fibrinogen concentrate: IMP will be administered while on cardiopulmonary bypass. Patients will be screened while on cardiopulmonary bypass (approx 1 hour before end of operation) using Rotational Thromboelastometry: FibTEM MCF. If MCF<7mm, patients will be randomised to IMP: placebo 2:1. Dose will be tailored to patient based upon measured FibTEM MCF and desired target range.; Study Entry : Registration and One or More Randomisations

**Intervention Type**

Drug

**Phase**

Phase II

**Drug/device/biological/vaccine name(s)**

Fibrinogen concentrate

**Primary outcome measure**

1. Fibrinogen concentration (measured using the Clauss method)
2. Fibrin polymerization (measured by rotational thromboelastometry Fib-TEM MCF) achieved within 5 minutes of completion of study drug

**Secondary outcome measures**

1. Efficacy
  - 1.1. Mediastinal drain losses in first 24 hours after PICU admission
  - 1.2. Requirement for delayed sternal closure due to clinical bleeding/tamponade
  - 1.3. Requirement for ancillary blood transfusions in first 24 hours post PICU admission
  - 1.4. Use of intra- and post-operative ancillary clotting products
  - 1.5. Fibrinogen levels and ROTEM variables at time points T4 T6

## 2. Safety

- 1.1. Incidence of major thrombotic event/thromboembolic associated complications
- 1.2. Allergic/hypersensitivity reaction to study drug

## Overall study start date

01/06/2014

## Completion date

02/03/2016

# Eligibility

## Key inclusion criteria

1. Congenital heart disease requiring non-emergency\* surgery on cardiopulmonary bypass
  2. Age range: >36 weeks corrected gestation
  3. Weight 2.5 to 12 kg
  4. Informed consent to participate
- \*Non-emergency is defined as surgery that can be delayed >24 hours following diagnosis of congenital heart disease

## Participant type(s)

Patient

## Age group

Child

## Sex

Both

## Target number of participants

Planned Sample Size: 90; UK Sample Size: 90

## Total final enrolment

111

## Key exclusion criteria

1. Known pre-existing inherited coagulopathy
2. Known pre-existing inherited thrombophilia
3. Recent, acute (within previous 2 weeks) thrombosis in a major vessel or thrombotic related major complications (as defined in protocol sections 2.43 and 7.3)
4. Administration of antiplatelet agents (e.g. aspirin) <48 hours prior to surgery
5. Known hypersensitivity/allergy to the study drug or similar products
6. History of anaphylaxis

7. Enrolment in another clinical trial in the previous 3 months
8. Parent/guardian unable to provide informed consent (this can include insufficient understanding of the trial, as judged by the clinician taking consent)
9. Major comorbidity likely to increase risk of mortality from surgical procedure
10. Significant renal/liver impairment within 2 days of planned surgery (creatinine > 2x Upper Limit of Normal, Alanine Aminotransferase > 2x ULN)

**Date of first enrolment**

01/06/2014

**Date of final enrolment**

02/03/2016

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Evelina Childrens Hospital**

London

United Kingdom

SE1 7EH

## **Sponsor information**

**Organisation**

Guy's and St Thomas' NHS Foundation Trust (UK)

**Sponsor details**

Kings Health Partners Clinical Trials Office

16th Floor, Tower Wing

Guy's Hospital

Great Maze Pond

London

England

United Kingdom

SE1 9RT

**Sponsor type**

Hospital/treatment centre

**ROR**

## Funder(s)

### Funder type

Industry

### Funder Name

CSL Behring

### Alternative Name(s)

CSL Behring LLC, CSL Behring GmbH, CSL

### Funding Body Type

Private sector organisation

### Funding Body Subtype

For-profit companies (industry)

### Location

United States of America

## Results and Publications

### Publication and dissemination plan

Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

Not provided at time of registration

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

| Output type                        | Details                                   | Date created | Date added | Peer reviewed? | Patient-facing? |
|------------------------------------|---|--------------|------------|----------------|-----------------|
| <a href="#">Basic results</a>      |   |              | 21/06/2019 | No             | No              |
| <a href="#">Results article</a>    | results                                   | 01/12/2020   | 23/11/2020 | Yes            | No              |
| <a href="#">Other publications</a> | mechanistic sub-study of the FIBCON trial | 09/11/2022   | 14/11/2022 | Yes            | No              |
| <a href="#">HRA research</a>       |   |              | 28/06      |                |                 |

