PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Evaluation of predelivery maternal fibrinogen as predictor for blood loss during childbirth

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

In this trial pregnant women schedule to undergo vaginal delivery are prospectively enrolled at admission to labour ward for delivery. Various parameters of blood coagulation in clinical routine, such as fibrinogen, are measured before birth and 48 h after birth and are related to the measured blood loss in the third stage of labour (after vaginal delivery).
The aim of this study is to investigate the predictive value of prepartum fibrinogen for blood loss during labour.

Brief Summary in Scientific Language

Background and Goal of Study: Postpartum haemorrhage (PPH) is defined as blood loss greater than 500 ml after vaginal delivery (1). PPH is potentially lifethreatening and the leading cause of maternal mortality worldwide. There are a variety of risk factors such as maternal hypofibrinogenaemia. Whether such low fibrinogen values by themselves play a role in the evolution of PPH, or only reflect the severity of hemorrhage is not clear (2).
The aim of the study is to determine, if the fibrinogen level in the first stage of labour is associated with the severity of bleeding in the third stage of labour.
Material and Methods: Pregnant women without elective cesarean delivery are prospectively enrolled at admission to the delivery ward. Fibrinogen concentration (measured according to Clauss), hb content and parameters of coagulation (in addition factor XIII concentration) are measured prepartum (at admission to the delivery ward). A second blood sample are drawn within 48 hours after delivery. Blood loss after vaginal delivery of the neonate (peripartum blood loss) is measured systematically by a calibrated drape under buttocks until active bleeding ceased.
Literatur: (1) WHO recommendations for the prevention and treatment of postpartum haemorrhage, Dept. of Reproductive Health and Research, WHO (2012)
(2) Charbit B. et al.,The decrease of fibrinogen is an early predictor of the severity of postpartum hemorrhage. J Thromb Haemost 2007; 5: 266–73.

Organizational Data

- DRKS-ID: **DRKS00007873**
- Date of Registration in DRKS: **2015/03/13**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **EA2/118/11 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- Free text: **coagulation and bleeding during labour and delivery, post partum haemorrhage (PPH)**
- Free text: **PPH in combination with fibrinogen concentration, parameters of plasmatic coagulation, factor XIII concentration and peripartum blood loss**

Interventions/Observational Groups

- Arm 1: **women with vaginal delivery, prepartum fibrinogen level and peripartum blood loss**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Prognosis**
- Assignment: **Single (group)**
- Phase: **N/A**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Uncontrolled/Single arm**

Purpose: **Prognosis**

Assignment: **Single (group)**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- Prepartal determination of fibrinogen concentration (measured according to Clauss)

- peripartum measurement of blood loss systematically by a calibrated drape under buttocks while active bleeding (Brenner Medical, München)

Secondary Outcome

- postpartum determination of fibrinogen concentration within 48 h

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Charité - Universitätsmedizin Berlin, Klinik für Geburtsmedizin, Campus Virchow-Klinikum Augustenburger Platz 1 D-13353 Berlin , Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/12/16**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2011/12/16**

Target Sample Size: **1000**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **14 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

- pregnant women at admission to the labour ward
- minimum age 18 years or parental permission
- consent of women for use of personal data

Exclusion criteria

- not able to speak and understand german
- doubt of ability to judge
- elective caesarean delivery

Addresses

- **Primary Sponsor**

Charité Universitätsmedizin Berlin, Klinik für Geburtsmedizin, Campus Virchow-Klinikum
Mr. Prof. Wolfgang Henrich,
Augustenburger Platz 1
13353 Berlin
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

- **Contact for Scientific Queries**

Charité Universitätsmedizin Berlin, Klinik für Geburtsmedizin, Campus Virchow-Klinikum

Contact for Scientific Queries

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URL: **[---]***

Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

CSL Behring GmbH,
Philipp-Reis-Str. 2,
65795 Hatterseim
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/05/31**

Trial Publications, Results and other documents

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*