Trial Description

Title

prospective Evaluation of the in - vitro Platelet function as well as the concentration of platelets in the cerebrospinal fluid in patients with aneurysmal SAH

Trial Acronym

PlaFuSah Study

URL of the trial

[---]*

Brief Summary in Lay Language

The goal of this analysis is the prospective evaluation of the platelet function as a predictive parameter with regard to the development of delayed stroke after aneurysmal subarachnoid haemorrhage.

Brief Summary in Scientific Language

The goal of this analysis is the prospective evaluation of the in vitro platelet function as a predictive parameter with regard to the development of delayed cerebral ischemia after aneurysmal subarachnoid haemorrhage

Organizational Data

- DRKS-ID: **DRKS00009244**
- Date of Registration in DRKS: **2015/08/26**
- 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.: **D480/15 , Ethikkommission der Christian-Albrechts-Universität zu Kiel**

Secondary IDs

Health condition or Problem studied

- ICD10: **I60 - Subarachnoid haemorrhage**

Interventions/Observational Groups

- Arm 1: **Platelet function will be determined using the PFA 100 test in patients with aneurysmal subarachnoid haemorrhage at different time points as well as on days with clinical or radiological evidence of DCI. Concentration of plaleteles in the cerebrospinal fluid will be simultaneously analysed if a CSF drainage is present.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- 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

DCI („delayed cerebral ischemia“) in the first 6 weeks

Secondary Outcome

outcome after 6 weeks: degree of disability after a stroke, using mRS (Modified Rankin Scale)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Kiel**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/08/16**
- Target Sample Size: **350**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

**Age > 18 years; aneurysmal SAH;
informed consent (if patient is not conscious - a custodian will be determined by the responsible legal institution); primary SAH; Aneurysm closure < 48 hours after rupture**

Exclusion criteria

non - aneurysmal SAH; fisher °I (no SAH visible on primary cranial CT Scan); pregnancy; life expectancy < 1 year

Addresses

- **Primary Sponsor**

  Neurochirurgische Klinik, UKSH Kiel
  Mr. Dr. med. Christian von der Brelie
  Arnold Heller Strasse 3
  24105 Kiel
  Germany

  Telephone: **00494315974801**
  Fax: **00494315974918**
  E-mail: **cvdb at gmx.net**
  URL: **http://www.uksh.de/neurochirurgie-kiel/**
- **Contact for Scientific Queries**

  Neurochirurgische Universitätsklinik Kiel
  Mr. Dr. med. Christian von der Brelie
  Arnold Heller Strasse 3

Contact for Scientific Queries

Neurochirurgische Universitätsklinik Kiel
Mr. Dr. med. Christian von der Brelie
Arnold Heller Strasse 3
24105 Kiel
Germany

Telephone: **00494315974801**
Fax: **00494315974918**
E-mail: **christian.vonderbrelie at uksh.de**
URL: **http://www.uksh.de/neurochirurgie-kiel/**

- **Contact for Public Queries**

Neurochirurgie Universitätsklinik Kiel
Mr. Dr. med. Christian von der Brelie
Arnold Heller Strasse 3
24105 Kiel
Germany

Telephone: **00494315974801**
Fax: **00494315974918**
E-mail: **christian.vonderbrelie at uksh.de**
URL: **http://www.uksh.de/neurochirurgie-kiel/**

Sources of Monetary or Material Support

- **Private sponsorship (foundations, study societies, etc.)**

Mehdorn Stiftung
Sternwartenweg 1
24105 Kiel
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **info at mehdorn-stiftung.de**
URL: **[---]***

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

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.*