Trial Description

Title

Thromboelastometry in Acute Hemorrhage Induced by Traumatic Injury of the Brain - a pilot study.

Trial Acronym

TAHITI-B

URL of the trial

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Brief Summary in Lay Language

Injuries to the head and brain (traumatic brain injury) can lead to potentially life-threatening intracranial bleeding. Depending on the mechanism of injury, potentially life-threatening bleeding can also occur anywhere else in the body. In these patients, early support of the body's own coagulation system is a key factor in bleeding control. However, the therapy with coagulation factors and blood products is associated with a number of risks. Therefore, point-of-care available laboratory tests - such as thromboelastometry - are increasingly used to guide individualised coagulation therapy. The goal of this pilot study is to evaluate the feasibility of thromboelastometric guided coagulation therapy in patients with traumatic brain injury and suspected bleeding.

Brief Summary in Scientific Language

Traumatic brain injury (TBI) remains to be a major health and socioeconomic problem. After TBI progressive intracranial hemorrhage is one of the most devastating reasons for secondary brain damage. The presence of coagulopathy after TBI has not only been associated with progression of intracranial hemorrhage but has also been linked to increased rates of mortality. Therefore, an early and aggressive therapeutic approach towards coagulopathy is desirable in this group of patients. However, it has become evident over the last decade that the empiric and uncontrolled use of blood products and coagulation factors is associated with serious adverse events. Thus, the possibility to rapidly identify coagulopathy and treat it in a goal-directed manner seems to be of utmost importance in patients with TBI. Rotational thromboelastometry (ROTEM®) is a viscoelastic point-of-care applicable method for global assessment of hemostasis that provides first results within a few minutes. Its use in guiding coagulation management in the trauma setting has widely spread over the last years. However, data on viscoelastic guided coagulation management in patients with TBI are still missing. Therefore, the aim of this multi-center, prospective pilot study is to assess the feasibility of implementing a ROTEM®-guided coagulation management algorithm in patients with TBI and suspected hemorrhage treated in centers that do not use ROTEM® as part of their routine clinical practice. According to an amendment to the study protocol, the number of patients to be included was adapted after recruitment of patients had begun.

Organizational Data

- DRKS-ID: **DRKS00011559**
- Date of Registration in DRKS: **2017/01/13**
- 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.: **EK134/16 , Ethik-Kommission an der Medizinischen Fakultät der RWTH Aachen**

Secondary IDs

Health condition or Problem studied

- ICD10: **S06 - Intracranial injury**
- ICD10: **D68 - Other coagulation defects**

Interventions/Observational Groups

- Arm 1: **Blood will be drawn to perform ROTEM® measurements (EXTEM and FIBTEM A5) as soon as possible after admission of a patient with severe TBI and suspicion of clinically relevant hemorrhage. These measurements will be used to guide the administration of hemostatic substances (tranexamix acid, fibrinogen or cryoprecipitate, platelet concentrate, prothrombin complex concentrate or fresh frozen plasma) in the included patients. The exact algorithm is described in the study protocol.**

Characteristics

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

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Assignment: **Single (group)**

Phase: **N/A**

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

Primary Outcome

The percentage of patients in whom the ROTEM® guided coagulation management algorithm has been started in regard to stepwise decision-making either in favor or against the suggested intervention, including action taken or the decision not to perform any intervention, according to EXTEM and FIBTEM A5 results within 60 minutes after admission of the patient to the hospital.

Secondary Outcome

1.) Time to first ROTEM® results after admission and after blood sampling. 2.) Time from admission to administration of agents suggested by the algorithm. 3.) Time from the first ROTEM® results to administration of agents suggested by the algorithm. 4.) Adherence to the algorithm and capturing reasons for non-adherence. (N.B.: Adherence will be defined as decision-making according to the algorithm within 60 minutes after initiation of the algorithm. Exact dosing of agents administered will not be taken into account.) 5.) ROTEM® results at 60 minutes after initiation of the algorithm. 6.) Additional systemic haemostatic interventions. 7.) Clinical outcome data as captured in the CENTER-TBI CRF.

Countries of recruitment

- BE **Belgium**
- DE **Germany**
- HU **Hungary**
- ES **Spain**

Locations of Recruitment

- University Medical Center **Antwerp, Belgium**

- University Medical Center **Aachen, Germany**
- University Medical Center **Pecs, Hungary**
- University Medical Center **Madrid, Spain**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/02/01**
- Target Sample Size: **40**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Additional Inclusion Criteria

1.) Clinical diagnosis of severe TBI (GCS≤8)
2.) Suspicion of clinically relevant hemorrhage
3.) Clinical indication for CT scan
4.) Presentation to the hospital within 24 hours after injury

Exclusion criteria

Severe pre-existing neurological disorder that would confound outcome asesements (according to CENTER-TBI)

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2018/01/01**

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Trial Publications, Results and other documents

- Paper **Gratz J, Güting H, Thorn S, Brazinova A, Görlinger K, Schäfer N, Schöchl H, Stanworth S, Maegele M. Protocolised thromboelastometric-guided haemostatic management in patients with traumatic brain injury: a pilot study. Anaesthesia. 2019;74:883-890. doi: 10.1111/anae.14670.**

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