Trial Description

Title

Sonographig Assessment of VEntricular hemorrhage- bedside detection of ventricular clearance via transcranial sonography

Trial Acronym

SAVE

URL of the trial

http://-

Brief Summary in Lay Language

**Intracerebral or intraventricular hemorrhages can be detected via computer tomographies (CT)or magnetic resonance imaging (MRI) .
All patients, so are participants of this study, are treated according to standards of the Departements of Neurology and Neurosurgery of the University Hospital of Freiburg and according to the guidelines of the German Stroke Association; participating in this study does not change therapy measures.
All patients receive a second CT-scan due to those standards, usually 3-7 days after occurence of the bleeding.
The aim of the study is to picture and measure the hemorrhage via transcranial sonography. Therefore, a transcranial sonography is performed on day 1 and the following days until the day of the second CT-scan. The localisation and volume of the hemorrhage is measured in all diagnostic mediums and compared. Therefore, sonographic pictures are evaluated by 2 different neurologists, CT- and MR-scans by a neuroradiologist. The aim is to show that transcranial sonography is a safe, precise and examiner-independent in intracerebral or intraventricular hemorrhages.**

Brief Summary in Scientific Language

**Via transcranial sonography it is possible to display cerebral structures and their pathologies. Especially, the ventricular system and the third ventricle can be displayed well and sonographies of the ventricular width correlate sufficiently with computer tomographies (CT; (Becker et al. 1994, Seidel et al. 1995, Kiphuth et al. 2011). Pathologies, such as intracerebral bleedings, can be depicted sufficiently via transcranial sonography (Seidel et al. 1995, Kukulska-Pawluczuk et al. 2012). Furthermore, the sonographic measurement of the size and volume of the hemorrhage correlate with values of CT-scans (Marti-Fabregas et al. 2005, Niesen et al. 2006, Perez et al. 2009). Therefore, transcranial sonography is a bed-side tool for follow-up of intracerebral hemorrhages (Perez et al. 2009) and diseases affecting the wifth of the third ventricle (Kiphuth et al. 2011).
The transcranial sonography shows several advantages compared to CT- or magnetic resonance imaging (MRI)- scans: it prevents patients' transports, is not based on x-rays, and can be used in agitated patients due to its shorter examination time Perez et al. 2009, Ovesen et al. 2014).
INtraventricular hemorrhages can be depicted sufficiently as hyperechogenic**

**structures (Mäurer et al. 1998, Kukulska-Pawluczuk et al. 2012).
Systematic studies of changes of echogenicity of venrricular bleedings do not exist so far. However, we suggest that transcranial sonography is a safe method for intraventricular bleedings as it is for intracerebral bleedings (Seidel et al. 1993).
This study aims to show that the transranial sonography is a safe, sufficient and examiner-independent method to display ventricular hemorrhages and their course of echogenicity.
In the future, CT-scans could be scheduled and their number even reduced according to sonographic measurements.**

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00008192**
- Date of Registration in DRKS: **2015/04/28**
- 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.: **463/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I61.5 - Intracerebral haemorrhage, intraventricular**
- ICD10: **I61.0 - Intracerebral haemorrhage in hemisphere, subcortical**

Interventions/Observational Groups

- Arm 1: **A transcranial sonography is performed in all patients with intraventricular or intracerebral hemorrhage displaying the ventricular system and hemorrhage. Sonography is performed every day until the second CT-scan. Results of ultrasound and CT- or MRI-scans are compared regarding echogenicity of the third ventricle, the Graeb-Score and the hemorrhage**

volume.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Correct display of intraventricular hemorrhage on day 1 via transcranial B-mode-sonography

Secondary Outcome

Correct display of a intraventricular hemorrhage on day 3-7
Volume and localisation of the bleeding (via Graeb-Score) comparing sonographic and CT-/MRI-images on day 1 and day 3-7 (day of second CT-scan)

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Neurologie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/04/21**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2015/04/21**

Target Sample Size: **100**

Monocenter/Multicenter trial: **Monocenter trial**

- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

age >18 and <85 years, diagnosis of a intraventricular or intracerebral hemorrhages via CT or MRI, symptom onset <12hours, positive informed consent

Exclusion criteria

insufficient transtemporal bone window

Addresses

- **Primary Sponsor**

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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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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.*