



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

Trial Description

Title

Differentiation between cerebral ischemia and intracerebral hemorrhage in patients with acute stroke.

Trial Acronym

BE FAST II

URL of the trial

[---]*

Brief Summary in Lay Language

We are collecting blood samples and clinical data of patients with symptoms of acute stroke within 6 hours of symptom onset. The laboratory analysis of GFAP (a brain protein) in the blood of patients may help us to differentiate between the two major subtypes of stroke, cerebral ischemia or intracerebral bleeding.

Brief Summary in Scientific Language

The aim of this prospective study is to estimate sensitivity, specificity as well as positive and negative predictive values of GFAP for differentiating between cerebral ischemia and intracerebral hemorrhage in patients admitted with symptoms of acute stroke.

Organizational Data

- DRKS-ID: **DRKS00004378**
- Date of Registration in DRKS: **2012/10/04**
- 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.: **236/05 , Ethikkommission des Fachbereichs Humanmedizin der Johann-Wolfgang-Goethe-Universität Frankfurt am Main**

Secondary IDs



Health condition or Problem studied

- ICD10: **I61 - Intracerebral haemorrhage**
- ICD10: **I63 - Cerebral infarction**

Interventions/Observational Groups

- Arm 1: **Blood draw in the process of emergency care/ management. No further study-related measures.**

Characteristics

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

Diagnostic accuracy of a GFAP biomarker test (ROC-analysis: sensitivity, specificity, predictive positive and negative value) for differentiating intracerebral hemorrhage from cerebral ischemia.

Secondary Outcome

Identification of possible correlation of GFAP-serum levels with localisation and size of the hemorrhage.

Countries of recruitment

- **DE Germany**

Locations of Recruitment



- University Medical Center **Charite (CSB), Berlin**
- Medical Center **Klinik für Neurologie, Herford**
- Medical Center **Klinik für Neurologie, Bad Homburg**
- Medical Center **Klinik für Neurologie, Wiesbaden**
- University Medical Center **Münster**
- University Medical Center **Dresden**
- University Medical Center **Halle Saale**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/05/03**
- Target Sample Size: **600**
- 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

symptoms of stroke < 6 hours, NIHSS >= 4 points

Exclusion criteria

stroke within the last 3 months, history of brain tumor, traumatic brain injury within the last 3 months

Addresses

■ Primary Sponsor

**Klinikum der Johann Wolfgang Goethe-Universität Zentrum der Neurologie und Neurochirurgie
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Sources of Monetary or Material Support

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

Roche Diagnostics GmbH
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URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2013/09/02**

Trial Publications, Results and other documents

- Paper **Foerch C, Luger S et al (2017), Clinical Chemistry 63:1: Glial Fibrillary Acidic Protein Serum Levels Distinguish between Intracerebral Hemorrhage and Cerebral Ischemia in the Early Phase of Stroke**

* 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.