

Trial Description

Title

Cerebral hemodynamics in patients with a history of preeclampsia

Trial Acronym

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URL of the trial

[---]*

Brief Summary in Lay Language

Preeclampsia is a leading cause of maternal and fetal morbidity and mortality worldwide. During the course of this hypertensive pregnancy-specific disorder, cerebral autoregulation is impaired. It is not yet known how long changes of cerebral hemodynamics persist after birth. Women with a history of preeclampsia have a long-term increased risk of stroke.

Our study compares the cerebral hemodynamics of mothers with and without a history of preeclampsia. Using ultrasound, we compare two mechanisms of cerebral hemodynamics: Cerebral autoregulation keeps cerebral blood flow at constant levels irrespective of varying systemic blood pressure values. Neurovascular coupling leads to increased blood supply of particularly active brain areas. Comparing the cerebral hemodynamics of mothers with and without a history of preeclampsia we want to improve follow-up care of women after preeclampsia.

Brief Summary in Scientific Language

Cerebral circulation is regulated by several mechanisms. Cerebral autoregulation keeps cerebral blood flow at constant levels irrespective of varying systemic blood pressure values. Slow oscillations of systemic and cerebral blood flow can be induced respiratorily by breathing slowly at 0.1 HZ. Physiologically the respiratory induced cerebral oscillations are time-shifted to the systemic oscillations in which the phase shift embodies functioning cerebral autoregulation (Kuo et al. 2003). Neurovascular coupling leads to increased blood supply of particularly active brain areas. For instance, visual stimulation leads to an increase of blood flow velocity in posterior brain areas. Both adaptive mechanisms can be evaluated by ultrasonic testing.

During symptomatic preeclampsia, cerebral autoregulation is impaired (Oehm et al. 2003, Oehm et al. 2006, Rosengarten et al. 2004, van Veen et al. 2013). Preeclampsia is a leading cause of maternal and fetal morbidity and mortality worldwide (Noris et al. 2005). Impaired cerebral autoregulation is regarded as the cause of neurological symptoms of eclamptic patients (Thomas 1998). Women with a history of preeclampsia have a long-term increased risk of stroke (Wilson et al. 2003, Bellamy 2007). In a preceding study we could show that cerebral autoregulation during mid-term pregnancy is well-preserved even in the case of impaired blood flow of the uterine arteries. Only women with a history of preeclampsia showed pathological values (Janzarik et al 2014). Also neurovascular

coupling is impaired years after preeclampsia (Martens et al., 2009). However it is still unclear for how long changes of cerebral hemodynamics persist after birth. Comparing the cerebral hemodynamics of mothers with and without a history of preeclampsia by ultrasound, we aim to improve follow-up care of women after preeclampsia.

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van Veen TR, Panerai RB, Haeri S, Griffioen AC, Zeeman GG, Belfort MA. Cerebral autoregulation in normal pregnancy and preeclampsia. Obstet Gynecol. 2013 Nov;122(5):1064-9.

Wilson BJ, Watson MS, Prescott GJ, Sunderland S, Campbell DM, Hannaford P, Smith WC. Hypertensive diseases of pregnancy and risk of hypertension and stroke in later life: results from cohort study. BMJ 2003 Apr 19;326(7394):845.

Organizational Data

- DRKS-ID: **DRKS00005665**
- Date of Registration in DRKS: **2014/01/23**
- 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.: **10/14 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1152-4974**

Health condition or Problem studied

- ICD10: **O14.9 - Pre-eclampsia, unspecified**

Interventions/Observational Groups

- Arm 1: **Transtemporal dopplersonographic examination of A. cerebri media and A. cerebri posterior to evaluate the cerebral hemodynamics (dynamic cerebral autoregulation and visual coupling) of women with a history of preeclampsia. Dopplersonographic findings will be correlated with clinical data, which will be inquired using a questionnaire.**
- Arm 2: **Transtemporal dopplersonographic examination of A. cerebri media and A. cerebri posterior to evaluate the cerebral hemodynamics (dynamic cerebral autoregulation and visual coupling) of women after a pregnancy without preeclampsia. Dopplersonographic findings will be correlated with clinical data, which will be inquired using a questionnaire.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Using a one-time dopplersonographic ultrasound examination, parameters of dynamic cerebral autoregulation (phase and gain) will be evaluated.

Secondary Outcome

Using a questionnaire history of cerebrovascular risk factors (hypertension,

diabetes, increased BMI) and possible ischemic cerebrovascular events will be inquired.

During the one-time dopplersonographic examination parameters of visual coupling (resting flow velocity, overshoot flow velocity, steady-state flow velocity) will be evaluated.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Geburtshilfe und Perinatologie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/02/07**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **55 Years**

Additional Inclusion Criteria

1. Women after at least one birth with or without preeclampsia, respectively. 2. Time interval to the last birth > 1 year and < 15 years. 3. Age 18 to 55 years. 4. Written informed consent to the study.

Exclusion criteria

1. Pregnancy at the time of study inclusion. 2. History of brain operation or brain tumor. 3. No ultrasound window for transtemporal ultrasound. 4. Epilepsy.

Addresses

■ **Primary Sponsor**

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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 complete, follow-up complete**

■ Study Closing (LPLV): **2014/11/20**

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.