

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

## Trial Description

### Title

**Prolongation of pregnancy in preeclampsia by therapeutic lipid-apheresis and its effect on fetal lipid metabolism**

### Trial Acronym

[---]\*

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**Preeclampsia is a disease which concerns about 6-8 % of all pregnancies and is the main cause of maternal and fetal morbidity and mortality. The cause of preeclampsia is still not defined and the sole therapy is preterm caesarean delivery. Our group could show in 2003 that in grave preeclampsia a accumulation of triglyceride-rich lipoproteins occurs, which is statistically associated with low birth weight, proteinuria and hypertension- the cardinal symptoms of preeclampsia. Therefore we propose lipidapheresis as lipid-modifying therapy for treatment of preeclampsia in order to prolong pregnancy and give the fetus more time to mature. In 2006 this approach was tested from Wang et al. in a pilot study with 9 patients utilizing "heparin-mediated extracorporeal low density precipitation" (H.E.L.P.) . So far we have treated six preeclamptic women with H.E.L.P. apheresis in a therapeutic attempt (Etikkommission nr. 457/12, vote of december 03,2012). We were able to prolong the pregnancies between 4 - 14 days (on average 10,5 days).**

**Due to these encouraging results we now want to perform a study (Etikkommission study nr. 222/14\_140801, vote of august 03,2014). In addition we want to find out whether the apheresis therapy influences the lipid concentration and lipid composition in cord blood.**

### Brief Summary in Scientific Language

**The sole available treatment for preeclampsia so far is caesarean section, which in early preeclampsia may cause high morbidity and mortality of the pre-term newborn. Our study intends to prolong pregnancy by treatment with H.E.L.P. apheresis. We document the clinical course and analyse in detail serum lipoproteins.**

**By analysing vasoactive receptors in cell cultures using biochemical parameters we attempt to clarify the pathogenesis of preeclampsia. In addition we want to find out whether the apheresis therapy influences the lipid concentration and lipid composition in cord blood.**

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

[---]\*

### Description IPD sharing plan

[---]\*

## Organizational Data

- DRKS-ID: **DRKS00004527**
- Date of Registration in DRKS: **2013/06/04**
- Date of Registration in Partner Registry or other Primary Registry: **2013/07/26**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **475/12 und 222/14\_140801 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

## Secondary IDs

- Primary Registry-ID: **NCT01967355 (ClinicalTrials.gov)**

## Health condition or Problem studied

- ICD10: **O14.9 - Pre-eclampsia, unspecified**
- ICD10: **[---]\* - [---]\***

## Interventions/Observational Groups

- Arm 1: **15 preeclamptic patients will be treated with H.E.L.P. apheresis (case group)**
- Arm 2: **15 pregnant women without preeclampsia (control group)**
- Arm 3: **cord blood from 15 newborn of preeclamptic women treated with apheresis (case group)**
- Arm 4: **cord blood from 15 newborn (> 37 week) (control group)**
- Arm 5: **cord blood from 15 premature babies (control group)**

## Characteristics

- Study Type: **Interventional**

Study Type: **Interventional**

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

### Primary Outcome

**Prolongation of pregnancy**

### Secondary Outcome

**Pregnant women with apheresis (case group): proteinuria, blood pressure, clinical symptoms, sonographic criteria in doppler ultrasound of umbilical vessels, quantity of amniotic fluid, concentrations of lipoproteins separated by density gradient ultracentrifugation, fibrinogen, sFlt-1 und PIGF, Lp-PLA2, blood cell count, haptoglobin, serum kreatinine, GOT, GPT, blood viscosity; in vitro: effect of biochemical parameters and diverse lipoprotein fractions on vasoactive receptors in cell cultures, analysis of parameters in the eluate of the apheresis filter;**

**pregnant women (control group): concentrations of lipoproteins separated by density gradient ultracentrifugation, fibrinogen, sFlt-1 und PIGF, Lp-PLA2, blood cell count, differential blood count, haptoglobin, serum kreatinine, GOT, GPT, blood viscosity;**

**cord blood (case and control group): pH, total cholesterol, triglycerides, lipidelectrophoresis, lipid density gradient ultracentrifugation, Lp(a), Lp-PLA2, sFLT, PIGF;**

**newborn (case group): weight, body height, pH of umbilical cord blood, APGAR, severe respiratory distress syndrome, duration of mechanical ventilation, intracranial hemorrhage (grade 1-4), necrotising enterocolitis, sepsis, duration of stay in intensive care unit, need of surfactant;**

**newborn (control group): weight, body height, APGAR**

### Countries of recruitment

- **DE Germany**

## Locations of Recruitment

## Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/04/16**
- Target Sample Size: **75**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

## Inclusion Criteria

- Gender: **Female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

## Additional Inclusion Criteria

**Pregnant women with early preeclampsia (< 32 week of pregnancy) and the following criteria of the Deutschen Gesellschaft für Gynäkologie und Geburtshilfe (DGGG, August 2010):**

- arterial hypertension during pregnancy
  - detectable proteinuria ( $\geq 1 +$  dipstick oder  $\geq 300$  mg/24h),  
and/or
  - intrauterine growth retardation (IUGR)
  - pathological Doppler-finding
- also:
- informed consent
  - age of mother > 18 years

## Exclusion criteria

**Pregnant women:  
every acute indication for immediate delivery;  
fetal blood cord:  
every medical reason against the blood withdrawal**

## Addresses

- **Primary Sponsor**

**Universitätsklinikum Freiburg, Institut für Klinische Chemie und**

### **Primary Sponsor**

#### **Laboratoriumsmedizin**

**Mr. Prof. Dr. med. Karl Winkler**  
**Hugstetter Str. 55**  
**79106 Freiburg**  
**Germany**

Telephone: **+49 761 270 35160**

Fax: **+49 761 270 34440**

E-mail: **karl.winkler at uniklinik-freiburg.de**

URL: **www.uniklinik-freiburg.de**

#### ■ **Contact for Scientific Queries**

**Universitätsklinikum Freiburg, Institut für Klinische Chemie und  
Laboratoriumsmedizin**  
**Mr. Prof. Dr. med. Karl Winkler**  
**Hugstetter Str. 55**  
**79106 Freiburg**  
**Germany**

Telephone: **+49 761 270 35160**

Fax: **+49 761 270 3440**

E-mail: **karl.winkler at uniklinik-freiburg.de**

URL: **www.uniklinik-freiburg.de**

#### ■ **Contact for Public Queries**

**Universitätsklinikum Freiburg, Institut für Klinische Chemie und  
Laboratoriumsmedizin**  
**Ms. Dr. med. Brigitte König**  
**Hugstetter Str. 55**  
**79106 Freiburg**  
**Germany**

Telephone: **0761/270-77210**

Fax: **0761/270-34440**

E-mail: **brigitte.koenig.zentrallabor at uniklinik-freiburg.de**

URL: **www.uniklinik-freiburg.de**

## **Sources of Monetary or Material Support**

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

**Universitätsklinikum Freiburg, Institut für Klinische Chemie und  
Laboratoriumsmedizin**  
**Mr. Prof. Dr. med. Karl Winkler**  
**Hugstetter Strasse 55**  
**79106 Freiburg**  
**Germany**

DRKS-ID: **DRKS00004527**

Date of Registration in DRKS: **2013/06/04**

Date of Registration in Partner Registry or other Primary Registry:  
**2013/07/26**

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

**Universitätsklinikum Freiburg, Institut für Klinische Chemie und  
Laboratoriumsmedizin  
Mr. Prof. Dr. med. Karl Winkler  
Hugstetter Strasse 55  
79106 Freiburg  
Germany**

Telephone: **+49 761 270 35160**

Fax: **+49 761 270 34440**

E-mail: **karl.winkler at uniklinik-freiburg.de**

URL: **www.uniklinik-freiburg.de**

## 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.