ISRCTN92923842 https://doi.org/10.1186/ISRCTN92923842

Microparticle orientated risk evaluation and prediction of pre-eclampsia among risk pregnancies

Submission date	Recruitment status	[ ] Prospectively registered
02/04/2009	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
28/07/2009	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/07/2009	Pregnancy and Childbirth	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
FI 1635/1-1

Study information

Scientific Title

Microparticle Orientated Risk Evaluation and Prediction of Pre-eclampsia Among Risk gravidas: a multicentre prospective phase I prognostic marker study

Acronym
MORE PrePARd

Study objectives
The objective is to elucidate whether serum microparticle concentrations of pregnant women with abnormal uterine perfusion (a high risk group), both measured at 20th week of gestation, can discriminate between women who will develop preeclampsia (case group) and those who will not (control group).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local ethics committee (Ethik-Kommission der Universitätsklinikum Jena) approved on the 26th August 2008 (ref: 2370-08/08)

Study design
Multicentre prospective blinded phase I prognostic marker pilot study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Pre-eclampsia/pregnancy

Interventions
Total of 80 - 100 pregnant women with abnormal uterine perfusion, including 20 women who develop pre-eclampsia during pregnancy (cases) and 60 - 80 woman who do not develop pre-eclampsia (controls). Patients with risk pregnancies for preeclampsia will be recruited for marker measurement between 19th and 21st week of gestation.

Experimental test:
Measurement of syncytiotophoblast microparticle (STBM) concentration in maternal serum at time of study inclusion.

Reference test:
Assessment of objective clinical symptoms of preeclampsia according to the German Society of Obstetrics and Gynecology (DGGG)-diagnostic criteria at 8-week intervals:
1. Hypertension defined as blood pressure (RR) systolic greater than or equal to 140 mmHg and /or diastolic greater than or equal to 90 mmHg, and
2. Proteinuria: Dipstick-Test greater than or equal to 1+ or greater than or equal to 300 mg total protein in 24-hour urine collection

There are two optional visits between the 19th and 21st week of gestation and birth: first visit at 27th to 29th week of gestation and second visit at 35th to 37th week of gestation to monitor these risk pregnancies. Final outcome will be assessed at 6 weeks post-partum.

Intervention Type
Other

Phase
Phase I

Primary outcome(s)
Development of pre-eclampsia during current pregnancy. Final outcome will be assessed 6 weeks post-partum either by study doctor or attending doctor.

Key secondary outcome(s))
Pre-eclampsia associated complications:
1. Differentiation early onset/severe and late onset/mild pre-eclampsia
2. Intra-uterine growth restriction (IUGR) or small for gestational age (SGA)
3. Induction of preterm labour/delivery
4. Intra-uterine foetal demise (IUFD)
5. Placental abruption

Final outcome will be assessed 6 weeks post-partum either by study doctor or attending doctor.

Completion date
20/05/2009

Eligibility

Key inclusion criteria
1. Abnormal uterine artery Doppler ultrasound
2. Singleton pregnancy
3. Appropriate-for-gestational-age foetus
4. 19th - 21st week of gestation
5. Healthy, normotensive gravidas
6. Women, all ages considered normal-risk pregnancy: 18 - 40 years

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

Key exclusion criteria
1. Concurrent participation in interventional clinical studies
2. Multiple pregnancy
3. Premature rupture of membrane (PROM)
4. Suspected/diagnosed infected amnion syndrome (IAS)
5. Pre-term labour/cervical incompetence
6. Foetal genopathia
7. Suspected foetal defects
8. Pre-existing maternal disease, e.g. diabetes mellitus, cardiovascular or renal disease

Date of first enrolment
20/04/2009

Date of final enrolment
20/05/2009

Locations

Countries of recruitment
Germany

Study participating centre
Abteilung für Geburtshilfe der Universitätsfrauenklinik Jena
Jena
Germany
07743

Sponsor information

Organisation
University Hospital of Jena (Universitätsklinikum Jena) (Germany)

ROR
https://ror.org/035rzkx15

Funder(s)

Funder type
Research council

Funder Name
German Research Council (Deutsche Forschungsgemeinschaft [DFG]) (Germany) (ref: FI 1635/1-1)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration