Determination of complement binding HLA-C antibodies with single-antigen-expressing cell lines (SAL) in pregnancies complicated by preeclampsia

Published: 17-06-2013
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We aim to determine an association between the presence of complement binding anti-paternal HLA-C antibodies and preeclampsia.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Maternal complications of pregnancy
Study type	Observational invasive

Summary

ID

NL-OMON38539

Source
ToetsingOnline

Brief title
Complement binding HLA-C antibodies in preeclampsia

Condition

- Maternal complications of pregnancy

Synonym
Pregnancy toxicosis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: ZonMW Agiko Stipendium. Dossiernummer

92003565

Intervention

Keyword: Complement, HLA-C antibodies, Preeclampsia, SAL

Outcome measures

Primary outcome

Presence of HLA-C IgG1 and/or IgG3

Secondary outcome

Presence of HLA-C IgG and IgM

Presence of HLA class I and II antibodies

Study description

Background summary

Preeclampsia is a relatively common but potentially dangerous disorder in human pregnancy, significantly contributing to maternal and neonatal morbidity and mortality. Recent evidence suggests preeclampsia to be associated with classical complement activation, with preference of C4d deposits at the syncytiotrophoblast at the fetal-maternal interface. The question is whether these complement deposits result from binding with antibody-antigen immune complexes at the trophoblasts. Therefore, in this study we focus on the detection of antibodies that target the paternal human leukocyte antigens (HLA) on the surface of the trophoblast: HLA-C.

Study objective

We aim to determine an association between the presence of complement binding anti-paternal HLA-C antibodies and preeclampsia.

Study design

We prospectively collect maternal blood samples and umbilical cord blood of women after uncomplicated, or preeclampstic pregnancies. We compare the presence of complement binding HLA-C antibodies in a retrospective case-control design.

Study burden and risks

The subjects will not be exposed to activities for this research. The maternal bloodsamples are taken immediately before or after delivery by competent nursesand during routine bloodsamples. Risks and side effects of taking blood are considered as nonexistent.
The umbilical cord blood is taken from the umbilical cord after delivery, there are no risks or side effect expected with this sampling.

Participation in the study will not directly benefit the subject, but the results may in future be important for other patients

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

We select primiparous women with an uncomplicated, term pregnancy (control) and preeclampsia (case) who deliver at the Leiden University Medical Center. Preeclampsia is defined as gestational hypertension (systolic pressure >= 140 mmHg and/or diastolic pressure >= 90 mmHg detected after 20th week of gestation) or worsening of preexistent hypertension and proteinuria (>= 0.3 gr/l/24hours).

Exclusion criteria

Maternal autoimmune diseases as antiphospholipid syndrome or SLE, drugs, use of immunosuppressive medication, intrauterine infections and bloodtransfusions or organ transplantions in medical history.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-07-2013
Enrollment:	132
Type:	Actual

Ethics review

Approved WMO

Date:	17-06-2013
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	21-08-2013
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL44413.058.13