

Regulatory T-cells in umbilical cord blood: the connection between the immunological background of preeclampsia and the birthorder effect of atopic offspring.

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In this pilot study we intend to measure Tregs in umbilical cord blood, in normal as well as in pregnancies complicated by preeclampsia, and will define their use as a predictor of the risk for developing allergic diseases in the child.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON29930

Source

ToetsingOnline

Brief title

Tregs in cord blood in preeclampsia

Condition

- Allergic conditions
- Neonatal and perinatal conditions
- Respiratory disorders NEC

Synonym

hayfever, pre-eclampsia, toxicosis

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: atopy, birthorder effect, preeclampsia, regulatory T cell

Outcome measures

Primary outcome

The number of Tregs in the umbilical cord blood and in the blood of the mother.

Atopy of the mother.

Secondary outcome

Does not apply.

Study description

Background summary

Over the last few decades there has been an increase in prevalence of atopic children. An interesting fact in this matter is that first born children are more prone to become atopic than their later born siblings. The cause of this effect remains unclear. Preeclampsia is a serious complication of pregnancy and although the exact cause has not been identified, it is clear that there is an immunological background. An observation made in preeclampsia is the fact that women pregnant for the first time have a three times higher risk for developing preeclampsia than women that have been pregnant before. We think regulatory T cells (Tregs) are a candidate for regulating the above mentioned processes.

Study objective

In this pilot study we intend to measure Tregs in umbilical cord blood, in normal as well as in pregnancies complicated by preeclampsia, and will define their use as a predictor of the risk for developing allergic diseases in the child.

Study design

The researcher will administer an interviewing questionnaire to the mother and father, regarding questions on atopy, obstetric history and smoking. One tube of blood will be drawn from the mother during a venapuncture for clinical purposes. One tube of umbilical cord blood will be drawn after birth of the placenta. The total time taken from the subjects is approximately one hour. Participation in the study will not produce any risks for the subject. In the blood of the mother specific IgE against inhalation allergens and foodallergens will be identified using UniCap. In both the blood of the mother and the child (cord blood) the number of Tregs will be identified using FACS-analysis. After the delivery information about obstetric history, current pregnancy and delivery will be collected from the clinical record. Analysis of the data will be done using SPSS 12.

Study burden and risks

The time needed to fill out the questionnaire is approximately 30 minutes. No further contact with the subject is required. No risks.

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

Pregnancy of 26 weeks and more.

Exclusion criteria

> 1 fetus in current pregnancy

Immunological disorders: HIV+, AIDS, immunodeficiencies.

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Basic science

Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 01-04-2006

Enrollment: 40

Type: Anticipated

Ethics review

Approved WMO

Application type: First submission

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	NL11434.042.06