Immune development in early life

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1. To describe the development of the nature of the immune system in early life in a profile of cytokines, chemokines and adipokines. 2. To evaluate less invasive methods like the use of saliva or less demanding methods like the use of dried bloods...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Immune disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON38195

Source
ToetsingOnline

Brief title
Immune development in early life

Condition

- Immune disorders NEC
- Viral infectious disorders
- Neonatal and perinatal conditions

Synonym
Allergy, Immune-mediated diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: TI Pharma

Intervention

Keyword: Cytokines, Immune maturation, Neonate, Saliva

Outcome measures

Primary outcome

A standard profile of the developing immune system will be generated with description of cytokines, chemokines and adipokines at different time points in the first week of life. Cord blood and peripheral blood samples will be obtained, the latter taken during the newborn (heel prick) screening and during the routine controls for glucose levels if applicable. From all children a sample of saliva will be taken simultaneously with the blood drawings. Cytokine, chemokine and adipokine profiles will be measured with a multiplex assay (Luminex xMAP technology).

Secondary outcome

We will evaluate pathological conditions similarly to detect early pathological changes and to use these as biomarkers for early intervention or preventive measurements. The pathological condition are sepsis, postnataal acquired CMV infection and perinatale effects of maternal PCOS.

Study description

Background summary

Neonatal exposure to antigens usually leads to tolerance. After birth, the immune system is primed by all kind of environmental factors and finally adult immune responses will protect efficiently against potentially harmful microbes. We are still badly informed about this immunological transition in the early neonatal period as we do not know what happens with this so called priming of the immune system. Available data are scarce, incomplete and mainly derived

from epidemiological studies and assumptions on biological processes from studies with animal models and human cord blood. A better insight in the maturation of the neonatal immune system is essential to understand the development of immune mediated diseases and for development of possible therapeutic or preventive strategies.

Study objective

1. To describe the development of the nature of the immune system in early life in a profile of cytokines, chemokines and adipokines.
2. To evaluate less invasive methods like the use of saliva or less demanding methods like the use of dried bloods spots for analysis of these profiles.
3. To describe the immunological development for pathological conditions like sepsis, postnatal acquired cytomegalovirus (CMV) infections and perinatal effects of maternal polycystic ovary syndrome (PCOS). Subsequently identifying biomarkers for these conditions.

Study design

Observational, descriptive and non-therapeutic study using cord blood, peripheral blood and saliva samples of newborns for in vitro experiments.

Study burden and risks

Risks and burden for the subjects are related to the drawing of the blood samples only and are brought to a minimum since there is a clinical indication to draw blood and this will be performed by experienced professionals. We will use a maximum of 3 samples and 0.5 ml extra blood will be drawn per sample. Extra blood will only be drawn when the total volume of drawn blood does not exceed 3 ml. A sample of saliva will be taken with a special swab approved for infants below 6 months of age. The participants will not directly benefit from the outcome of the study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

- Healthy term (37-42 weeks) newborns born in the hospital on maternal indication after an uncomplicated pregnancy and delivery
- Diabetes group: Newborns from mothers with diabetes mellitus or diabetes gravidarum at risk for hypoglycaemia and who will routinely have several glucose controls in the first 24-48 hours after birth
- Sepsis group: Newborns with a clinical diagnosed sepsis
- PCOS group: Newborns from mothers with PCOS
- CMV infection group: Preterm born children (AD<32 weeks) with a postnatal acquired CMV infection and matched controls with similar clinical and patient characteristics but without a CMV infection

Exclusion criteria

- Complications during pregnancy (HELLP, pre-ecmplampsia, infection) except for the pathological conditions under investigation
- Smoking during pregnancy
- Use of immune-modulating medication during pregnancy
- Use of antibiotics by the mother in two weeks before delivery
- Perinatal complications not related to inclusion criteria
- Prematurity (GA<36 weeks) or dysmaturity (birth weight < -2 SD) except for the preterm born children in the CMV infected population or their controls
- Immunological disorders like velocardiofacial syndrome, DiGeorge syndrome
- Chromosomal disorders

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-12-2012
Enrollment:	205
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-09-2014
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37428.041.12