The role of innate immunity and regulatory T cells in the development of immune tolerance in early life.

Published: 19-05-2009
Last updated: 06-05-2024

To understand the development of immunological tolerance for allergens in young children.

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

Summary

ID

NL-OMON33767

Source
ToetsingOnline

Brief title
The development of immunological tolerance in early life

Condition

- Allergic conditions

Synonym
allergy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Allergic disease, Early life, Immunological tolerance

Outcome measures

Primary outcome

Development in time of number, phenotype and function of several subsets of mononuclear cells with special attention for T regulatory cells. Levels and effect of immune modulating factors such as adenosine, PGE2 and innate stimuli on the function of immune cells over time.

Secondary outcome

Not applicable

Study description

Background summary

There has been a clear and worrying increase in a diverse range of allergic diseases, such as asthma, eczema, food allergy and hay fever, which are all associated with an underlying failure of immune tolerance to allergens. Development of immune tolerance is a critical process in early life and seems to be influenced by external factors such as infections, gut colonization and nutritional immune modulating factors. The mechanisms of immunological tolerance induction in young children are largely unknown. A better insight in these processes and the external factors that influence them is needed to be able to develop treatment strategies aiming at the prevention of allergic disease in high risk children.

Study objective

To understand the development of immunological tolerance for allergens in young children.

Study design

Cord blood and blood at one or several time points during the first year of life will be obtained from *immunologically healthy* children. Peripheral Blood

Mononuclear Cells (PBMC) and serum will be isolated and cellular and humoral immune factors hypothesized to be important in the induction of immune tolerance will be studied. At each time point questionnaires will be taken to obtain information about family history for allergic disease and the allergic status of the child at time of blood draw. At the day of the first surgical intervention 30 ml blood will be drawn from the mother as well.

Study burden and risks

Risks and burden for the subjects are related to blood withdrawals only and brought to a minimum. The blood withdrawals occur under general anaesthesia before surgery and will be executed by experienced professionals. The number of blood withdrawals depends on the number of surgical interventions, with a maximum of 4 blood withdrawals and 10 ml per withdrawal (in one year). 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

Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- antanatal diagnosed birthdefect such as schizis, duodenal atresia or orthopedic problems
- uncomplicated pregnancy and delivery
- birth planned in UMCU/WKZ
- a term delivery
- availability of cordblood
- one or more times surgery in the first year of life

Exclusion criteria

Complications during pregnancy (HELPP, infection)
Use of immune modulating medication during pregnancy
Smoking during pregnancy
Perinatal complications
- Prematurity (<36 weeks) or dysmaturity (birthweight - Use of antibiotics by the mother in the two weeks before delivery
- Use of antibiotics by the child in the first two weeks of life
- Immunological disorders such as VCF, DiGeorge
- Chromosomal disorder
- Perinatal infection

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):	23-06-2011

Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	19-05-2009
Application type:	First submission
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	NL24493.041.08