Translational research to study the role of regulatory cells in allergy early in life and the induction of regulatory cells in cord blood

Published: 29-05-2007
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Objective: How do T cells in cord blood respond to heat shock proteins, allergens and anti-CD3 Are stimulus specific Tregs induced during these responses and can these responses be suppressed by naturally occurring cord blood Tregs in vitro.

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

Summary

ID

NL-OMON31515

Source
ToetsingOnline

Brief title
Regulatory T cells in cord blood

Condition

- Allergic conditions

Synonym
allergy, atopic disease

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

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

Intervention

Keyword: allergy, cord blood, heat shock protein, regulatory t cells

Outcome measures

Primary outcome

Main study parameters/endpoints: Cytokine production profile, character of

immune cells of full term newborns and functionality of naturally occurring

regulatory T cells as well as induced regulatory T cells.

Secondary outcome

not applicable.

Study description

Background summary

Rationale: According to the hygiene hypothesis, the increase in the prevalence of allergic disorders in the past decades is due to a reduced microbial burden in childhood in westernized countries. In other immune diseases it has been shown that regulatory T cells play an important role in controlling the disease. Our group has shown that regulatory T cells can be induced with heat shock proteins (HSP). It can be hypothesized that in allergic disease the regulatory T cells are insufficient in number or in function at birth and that the immune status can be positively influenced by inducing these Tregs.

Study objective

Objective: How do T cells in cord blood respond to heat shock proteins, allergens and anti-CD3 Are stimulus specific Tregs induced during these responses and can these responses be suppressed by naturally occurring cord blood Tregs in vitro.

Study design

Study design: In vitro study with immune cells isolated from cord blood.

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Risks and burden for subjects are considered negligible.

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

full term newborns
high risk: (inhalation or food) allergic pregnant woman
low risk: (inhalation or food) allergy not present with pregnant woman, nor with the to be father or the to be brothers and sisters (now or earlier in life)

Exclusion criteria

gebruik van immuun modulerende medicatie tijdens de zwangerschap
roken tijdens de zwangerschap

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	27-05-2008
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO Date:	29-05-2007
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-08-2007
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-10-2008
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	NL16498.041.07