Characterisation of regulatory T cells and cytokine production in children diagnosed with asthma

Published: 29-01-2008
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To characterise the number, phenotype and functionality of regulatory T cells and cytokines produced in the peripheral blood of children diagnosed with asthma.

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders congenital
Study type	Observational invasive

Summary

ID

NL-OMON33976

Source
ToetsingOnline

Brief title
Regulatory T cells in asthma

Condition

- Respiratory disorders congenital
- Allergic conditions
- Bronchial disorders (excl neoplasms)

Synonym
Airway hyperresponsiveness, bronchusobstruction

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: GlaxoSmithKline,Nederlands AsthmaFonds

en GSK

Intervention

Keyword: Asthma, Children, Cytokines, Regulatory T cell

Outcome measures

Primary outcome

Number, phenotype and functionality of regulatory T cells in the peripheral

blood.

Secondary outcome

Cytokine analysis in the peripheral blood

Study description

Background summary

Of all newborns, 33% suffer from at least one period of wheezing before the age of 3 years. Of these so-called early wheezers (EW), only 40% will continue to wheeze between the age of 3 and 6 years (persistent wheezers=PW). At the age of 6 years PW, also designated to have asthma, can be differentiated from so-called transient wheezers (TW) who did not continue to wheeze between the age of 3 and 6 years. Attempts to differentiate PW from TW in early infancy have so far failed. In the related DART (diagnosis of asthma with regulatory T cells)-project proposal we hypothesize that Tregs play a role in the development of asthma and that TW and PW differ in either number, phenotype or functionality of Tregs. In order to establish the best immunological parameters and experimental assays to study in the DART-project it is important to first identify the main differences, and ways to best identify these differences, in number, phenotype and functionality of regulatory T cells and in cytokine production between children diagnosed with asthma and healthy children.

Study objective

To characterise the number, phenotype and functionality of regulatory T cells and cytokines produced in the peripheral blood of children diagnosed with asthma.

Study design

A pilot study including in vitro studies on peripheral blood of children diagnosed with asthma and of a healthy control group.

Study burden and risks

The risks and burden for subjects in this study are considered negligible. Blood will be taken at the same time as routine blood withdrawal, as much as possible. The subjects in the control group will be asleep/anaestitised at the time of blood withdrawal. A maximum of 2 blood samples of 20ml during the whole study will be taken.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Diagnosis asthma for more than one year
Use of inhaled corticosteroids for more than one year
Lung function reversibility of more than 10%
RAST test performed
OR
No asthma

Exclusion criteria

The use of systemic immune modulating medication at the time of blood withdrawal and/or 6 weeks before blood withdrawal. Active infection at the time of blood withdrawal and/or the use of antibiotics at the time of blood withdrawal.
OR
Allergies and autoimmune diseases.

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):	06-03-2008
Enrollment:	120
Type:	Actual

Ethics review

Approved WMO Date:	29-01-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	04-03-2008
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	24-03-2009
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-09-2009
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	NL19836.041.07