Does a different number, phenotype and/or function of regulatory T cells contribute to the development of asthma?

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To assess whether TW and PW show differences in number, phenotype or function of regulatory T-cells in peripheral blood samples. Details on study determinants will be based on the outcome of the pilotstudy (Regulatory T cells in asthma; PREDART0807...

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

Summary

ID

NL-OMON31752

Source
ToetsingOnline

Brief title
The role of regulatory T cells in the development of asthma

Condition

- Respiratory disorders congenital
- Autoimmune disorders
- Bronchial disorders (excl neoplasms)

Synonym
bronchusobstruction, recurrent infant wheezing

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Er subsidie verkregen van het Nederlands astma fonds (NAF) en aanvullend van GSK en het WKZ onderzoeksfonds. Kopie van deze toekenningen treft u als bijlage aan (addendum K1 en K3),GlaxoSmithKline

Intervention

Keyword: asthma, diagnosis, regulatory T cell, wheezing

Outcome measures

Primary outcome

Study endpoint: transient or persistent wheezing (= asthma) at age 6 years.

Study determinants: number, phenotype and functionality of regulatory T cells

in the peripheral blood of early wheezers at age 3 and 5 years. Details on

study determinants will be based on the outcome of the pilotstudy (Regulatory T

cells in asthma; ABR nummer 19836) preceding the analysis of the samples of

this prospective study.

Secondary outcome

Secondary determinants:

Questionnaires: WRC (Weekly Record Card) and questionnaire based upon the ISAAC

and PIAMA studies.

Lung function: RINTat the age of 3,4,5 and 6 years of age; Volume flow curves

before and after β2-mimetics at the age of 6 years.

eNose measurement at the age of 3 and 6 years.

Peripheral blood: cell numbers and Immunoglobin E levels (total and specific

IgE for most common food and inhalent allergens).

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. Attempts to differentiate PW from TW in early infancy have so far failed. In this 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.

Study objective

To assess whether TW and PW show differences in number, phenotype or function of regulatory T-cells in peripheral blood samples. Details on study determinants will be based on the outcome of the pilotstudy (Regulatory T cells in asthma; PREDART0807) preceding the analysis of the samples of this prospective study.
Furthermore differences in lung function and eNose measurements of transient and persistent wheezers will be assessed between the age of 3 and 6 years.

Study design

Etiological observational longitudinal study with a follow-up of 3 years.

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. A maximum of one blood sample at the age of 3 and 5 years will be taken as part of this study, also once yearly a full physical examination and lung function test will be performed. At the age of 3 and 6 years an eNose measurement will be performed. Furthermore a questionnaire will be filled out and 4 times a year during 2 weeks a weekly record card (WRC) will be filled out.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

patient is early wheezer
patient is 3 years of age

Exclusion criteria

The use of systemic immune modulating medication at the time of blood withdrawal and/or 6 weeks before blood withdrawal. The presence of an active infection at the time of blood withdrawal.

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):	19-06-2008
Enrollment:	175
Type:	Actual

Ethics review

Approved WMO Date:	03-03-2008
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	29-07-2008
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	NL16411.041.07