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

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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.

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|---|---|
| **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

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| 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 |