Immunological phenotype of asthma severity (iPhase)

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Our main objective is the characterization and comparison of interactions/ phenotype differences in DCs, Th cells and ILC2s obtained from asthma patients with controlled, partly controlled and uncontrolled clinical symptoms and healthy controls.

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

Summary

ID

NL-OMON44844

Source
ToetsingOnline

Brief title
iPhase

Condition

- Other condition

Synonym
Asthma, respiratory disorder

Health condition

astma patiënten

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W,Longfonds

Intervention

Keyword: Asthma, Immunology

Outcome measures

Primary outcome

Cell numbers and activation of Th subsets, DCs, ILC2s and granulocytes will be determined in peripheral blood and induced sputum of controlled, partly controlled and uncontrolled asthma patients and healthy controls.

Secondary outcome

- To compare the differences in activation status in DCs, and to identify correlations with immunological and clinical disease phenotype
- To compare the differences in activation status in T cell subsets, and to identify correlations with immunological and clinical disease phenotype
- To establish whether T helper cell polarization by DCs is altered in asthma patients
- To find correlations between ILC2 numbers and characteristics and immunological and clinical disease phenotype

Study description

Background summary

Asthma is a chronic heterogeneous disease of the airways. Patients with controlled asthma are characterized by a T helper (Th) 2 mediated eosinophilic inflammation, while uncontrolled asthma patients often display a neutrophilic

inflammation, associated by Th17 cells. Different immune cells, such as dendritic cells (DCs), Th cells, Group 2 innate lymphoid cells (ILC2s) and granulocytes play an important role in the pathology of both controlled and uncontrolled asthma. Therefore differences in the numbers of these immune cells as well as their activation states could provide more insight in differentiating controlled from uncontrolled asthma.

Study objective

Our main objective is the characterization and comparison of interactions/ phenotype differences in DCs, Th cells and ILC2s obtained from asthma patients with controlled, partly controlled and uncontrolled clinical symptoms and healthy controls.

Study design

In this study we aim to investigate cell number, phenotype, activation and gene expression in different immune cells in peripheral blood and induced sputum of controlled, partly controlled and uncontrolled asthma patients and healthy controls.

Study burden and risks

From asthma patients peripheral blood and induced sputum are taken during visitation. We estimate that participation in this study will pose a minimal additional risk of complications and patient discomfort. For healthy volunteers, withdrawal of peripheral blood and induced sputum is reported to be a safe procedure. Participants will not have direct personal benefit from participating in this study. The results from this study could be beneficial for the patient population. Healthy volunteers will receive a financial compensation.

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

In order to be eligible to participate in this study, a subject must meet one of the following criteria:
- Diagnosis of asthma confirmed by at least one of the following as assessed at least once during the 5 past years before the study:
- 1. Reversibility to β2-agonists as shown by an increase from baseline in FEV1>= 12% predicted and >= 200 ml after 400 µg inhaled salbutamol or equivalent;
- 2. Bronchial hyper-responsiveness (BHR) to metacholine (PD < 1.76) or histamine (PD < 2.59) as measured by standardized methods.
- 3. Peak-flow variability of >20% ((PEFmax - PEFmin)/PEFmax) over a period of 14 days.
- 4. Fall in FEV1>12% and >200ml when tapering of treatment (ICS, oral steroid, LABA and/or LTRA). ;We will include patients diagnosed with asthma and a recent (< 12 monts) metacholine provocation test, or histamine provocation test (PD20 < 1.76 mg). These test are performed in a standardized manner in both centers.
o In this study we will compare three different asthmatic phenotypes. These phenotypes will be determined based on clinical features and inflammatory sputum profile;
- Use inhaled corticosteroids daily and β2-agonists as required;
- Given written informed consent;
- Age: 18 - 50.

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:;- received systemic corticosteroid therapy (>= 7.5 mg/kg) within three months prior to inclusion;

- no use of inhaled corticosteroids and β2-agonists
- BMI > 35;
- Smoking > 10 pack years;
- Other diseases which could influence pulmonary function and/or the immune system such as:
o A possible infection of the upper- or lower respiratory tract 4 weeks prior to the collection of materials;
o Chronic obstructive pulmonary disorder (COPD) in the medical history;
o Auto-immune diseases such as systemic lupus erythematosus (SLE), rheumatoid arthritis (RA), myasthenia gravis or Goodpasture*s syndrome;
o Malignancies;
o Human immunodeficiency virus (HIV);
o Pregnancy;
o Other allergies except for allergic rhinitis.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-10-2015
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO

Date:	20-02-2015
Application type:	First submission

Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	19-05-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL50922.078.14