PROtective Microbial SubstancEs: a nasal challenge and biopsy study in HDM allergic patients and healthy subjects.

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

Summary

ID

NL-OMON45249

Source
ToetsingOnline

Brief title
PROMISE

Condition

- Allergic conditions

Synonym
allergic rhinitis, house dust mite allergy

Research involving
Human

Sponsors and support

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

Intervention

Keyword: adult, house dust mite allergy, immune modulation, nasal challenge

Outcome measures

Primary outcome

Nasal response to house dust mites after challenge

Secondary outcome

Several laboratory outcomes: Cellular composition within the nasal cavity tissue ; Epigenetic profile of isolated antigen-presenting cell populations; Cytokine production and activation status of dendritic cells and T cells stimulated with helicobactor and Schistosoma molecules; Microbiome composition within the nasal cavity as determined by 16s rRNA gene-based sequencing; RNA sequencing analysis of isolated antigen-presenting cells; Tryptase and cytokine levels within the fluid of the nasal cavity as a measure of induced inflammation. Analysis to IL C2 cells.

Study description

Background summary

In recent decades the prevalence of allergic diseases such as rhinitis and asthma have increased substantially. Treatment is restricted to allergen avoidance, pharmacotherapy and immunotherapy. The latter therapy is capable to modify the allergic reaction, to decrease symptoms, to influence the natural course of disease and to prevent the development of asthma. This therapeutic modality is however time consuming, burdensome and not without side effects. Thus, there is a need for new and innovative ways of treatment. Certain gastro-intestinal bacteria like Helicobacter pylori and helminth parasites were shown to protect against allergic airway disease and asthma

Study objective

The study is focused at developing new ways of treating allergic disorders. With this study we aim at evaluating the effects of helicobacter and Schistosoma molecules on nasal tissue stimulated by allergen exposure. The study will clarify mechanisms and identify potential molecules eligible for treatment of allergic patients in the future.

Study design

Nasal biopsies will be taken from patients with allergic rhinitis based on a HDM allergy and healthy subjects a week before and a day after a series of 3 nasal provocation tests on consecutive days. At baseline subjects will be screened with a questionnaire and skin test. Blood samples will be taken. We aim to recruit 30 patients and 30 healthy subjects. The duration of the study amounts two weeks for individual participants.

Intervention

Skin tests, nasal biopsies, nasal provocation, blood sampling

Study burden and risks

The study requires 6 visits, limited burden from skin tests and blood sampling. Slight discomfort from nasal challenge (sneezing, watery discharge, blockage) and biopsy with a sporadic change of bleeding after the biopsy.

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

Patients:
.18-50 years
.Clinically relevant moderate to severe allergic rhinitis as assessed by the ARIA criteria due to a sensitization for house dust mite
-Positive nasal challenge test to HDM
-Signed informed consent;Healthy subjects:
-18-50 years
-Absence of allergic rhinitis or other nasal disorders
-Negative skin prick test to HDM, birch pollen, grass pollen, cat and dog or other animals the patient is in daily contact with.
-Signed informed consent

Exclusion criteria

Patients:
-Inability to stop nasal corticosteroids 3 weeks and antihistamines 3 days before the provocation
- Allergy to animals the patient is in daily contact with pets
-Immunological diseases, cardiovascular diseases or malignity
-Previous or current immunotherapy
-Nasal polyps
-Unable to speak and understand the Dutch language properly.
-Not willing to comply with the study procedures
-Pregnancy;Healthy subjects
* Anatomical or other disorders of the nose
* Language barrier
* Pregnancy

Study design

Design

Study type:	Interventional
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):	29-08-2017
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO Date:	12-01-2017
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	17-08-2017
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	22-11-2017
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	NL58623.078.16