The consequences of mepolizumab-mediated depletion of eosinophils on adaptive and innate immune responses.

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In 15 patients of whom sputum will be collected (not in the other participating patients) :does depletion of eosinophils disturb the balance between Th2/Th1/Th17 cells in peripheral blooddoes depletion of eosinophils chance CD8 memory responses in...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Allergic conditions
Study type	Observational invasive

Summary

ID

NL-OMON45798

Source
ToetsingOnline

Brief title
MEPO-AIR

Condition

- Allergic conditions
- Bronchial disorders (excl neoplasms)

Synonym
adaptive and innate defense, immune system

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: adaptive_immunity, anti-IL5, innate_immunity, severe_asthma

Outcome measures

Primary outcome

genotyping white blood cells

humoral parameters and cellular differentiation of mucosal tissue (sputum and

nasal lavage)

Secondary outcome

n.a.

Study description

Background summary

Eosinophilic granulocytes in murine studies display important immune-modulatory properties on both the adaptive and innate immune response. Treatment of severe asthma patients with anti-IL-5 (mepolizumab) will result in patients without eosinophils. In this study we will examine the effect of depletion of eosinophils on the adaptive and innate immune response. In addition we will search for a biomarker that can serve as a predictor of efficacy.

Study objective

In 15 patients of whom sputum will be collected (not in the other participating patients) :
does depletion of eosinophils disturb the balance between Th2/Th1/Th17 cells in peripheral blood
does depletion of eosinophils chance CD8 memory responses in peripheral blood.
does depletion of eosinophils affect IgA and M1/M2 macrophage response at mucosa

In all patients we will search for a predictive biomarker.

Study design

Before mepolizumab treatment, one month after first dose and 9-12 months after

start blood will be drawn, a nasal lavage and a sputum will be induced.

Study burden and risks

per visit (3 times) blood will be drawn,a nasal lavage obtained and a sputum induced. The burden and risk are being considered as minimal.

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

severe asthma

Exclusion criteria

anemia, very low white blood cell count, anti-inflammatory and/or immunosuppressive medication other than used to treat asthma

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	100
Type:	Anticipated

Ethics review

Approved WMO

Date:	13-10-2017
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL56770.018.16