Analyse van uitgeademde lucht om de respons op behandeling met mepolizumab te voorspellen in patiënten met ersntig astma.

No registrations found.

Ethical review	Not applicable
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26797

Source
Nationaal Trial Register

Brief title
EXPREME

Health condition

Severe Asthma

Sponsors and support

Primary sponsor: Amsterdam UMC, University of Amsterdam
Source(s) of monetary or material Support: Dutch Lung Foundation

Intervention

Outcome measures

Primary outcome

- eNose ‘Breathprints’ (signature of mixtures of volatile organic compounds (VOCs) in exhaled

breath)

Secondary outcome

-Absence of exacerbations during 12 months after initiation of mepolizumab therapy.

-Improvement of Asthma Control Questionnaire (ACQ)-score by 0.5 points over 6 months.

-Decrease of oral corticosteroid (OCS) use by 50% after 12 months.

-Any switch of biological therapy.

Study description

Background summary

-

Study objective

The analysis of molecular profiles in exhaled breath by an electonic nose (eNose) is able to:

a. Discriminate between patients with severe asthma who respond to treatment with mepolizumab and those who do not respond to mepolizumab with at least 85% accuracy.

b. Replicate the findings in a. with at least 80% accuracy in an external validation.

Study design

Baseline, 6 months, 12 months

Intervention

Niet van toepassing

Contacts

Public

-
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Eligibility criteria

Inclusion criteria

- Adult patients with severe refractory eosinophilic asthma who are treated with Mepolizumab.

-Poor asthma control or frequent (≥2 per year) exacerbations, despite high-intensity treatment while alternative diagnoses have been excluded, comorbidities are treated and compliance has been checked.

-Peripheral blood eosinophil levels ≥150 cells/µl.

Exclusion criteria

- Alcohol use <12 hours prior to measurement.

- Unwillingness or inability to comply with the study protocol for any other reason.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial

Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-01-2016
Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL7128
NTR-old	NTR7474
Other	METC AMC. The MEC of the AMC ruled that the Medical Research Involving Human Subjects Act (WMO) does not apply to the study and that an official approval of this study by the MEC is not required. : W14_112 # 14.17.0147

Study results