

the Application of an Electronic Nose in the Early detection of Aspergillosis II

Published: 19-11-2012

Last updated: 26-04-2024

1. To establish whether serial exhaled breath analysis using eNose can detect invasive pulmonary aspergillosis in patients with prolonged chemotherapy induced neutropenia (neutrophil counts

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Haematological disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON39283

Source

ToetsingOnline

Brief title

The AENEAS II study

Condition

- Haematological disorders NEC
- Fungal infectious disorders
- Respiratory tract infections

Synonym

Aspergillosis, Invasive Pulmonary Aspergillosis

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - Aspergillosis, - Early-detection, - Electronic nose, - Prolonged neutropenia

Outcome measures

Primary outcome

Exhaled molecular profiles (by eNose and GC-MS) and the accuracy with which serial analysis of these profiles can discriminate between patients with probable or proven invasive pulmonary aspergillosis and neutropenic controls in terms of sensitivity, specificity and accuracy of the predictive algorithm.

Secondary outcome

1. Individual biomarkers and proteomic profiles in BAL fluid, exhaled air and serum predictive for invasive pulmonary aspergillosis, determined by different mass spectrometry techniques.
2. The alteration in the distribution of the pulmonary microbial community in neutropenic subjects developing invasive pulmonary aspergillosis compared to neutropenic subjects who do not.

Study description

Background summary

Patients with prolonged chemotherapy-induced neutropenia are at risk for invasive pulmonary aspergillosis (IPA). Incidence of IPA in this population is somewhere around 8-14% and mortality is high. Diagnosing IPA is complex, symptoms are non-specific and available diagnostic tools are either invasive or have low sensitivity and specificity. This often results in a diagnostic delay, with patients developing more extensive disease and in the meantime, increasing the mortality. Therefore, improved (non-invasive) diagnostic tools are desirable. In several diseases analysis of exhaled breath (using eNose) showed to be a promising diagnostic tool. This is potentially a fast, easy-to-perform and cheap addition to the diagnostic arsenal, improving diagnostic accuracy and

reducing the mortality of the infectious complications associated with the treatment of hematological diseases.

Study objective

1. To establish whether serial exhaled breath analysis using eNose can detect invasive pulmonary aspergillosis in patients with prolonged chemotherapy induced neutropenia (neutrophil counts $<0.5 \times 10^9$ for more than 7 days).
2. To establish whether serial exhaled breath analysis in this group of patients can detect invasive pulmonary aspergillosis at an earlier time point than using the current state-of-the-art diagnostic strategy.
3. To find specific biomarkers in serum, exhaled breath condensate, serial collected exhaled breath and broncho-alveolar lavage fluid by mass spectrometry, aimed to accurately diagnose invasive pulmonary aspergillosis.
4. To construct an airway microbiome in patients with prolonged neutropenia at different time points, comparing patients who develop invasive pulmonary aspergillosis with neutropenic patients who do not, in order to get more insights in the pathogenesis of invasive pulmonary aspergillosis.

Study design

Single center prospective cohort study

Study burden and risks

In this study there are no major risks and/or discomforts involved; discomfort for the patient will be minimized by the involvement of only qualified professionals in the procedures. The patients themselves will not directly benefit from participating in this investigation. However, the population may benefit from this study in the future if these novel diagnostic procedures (f.e. exhaled breath analysis) prove to be applicable in clinical settings. As such, we consider the balance between risks and discomfort for patients (low) and benefit for the future population (potentially high) acceptable.

Contacts

Public

Academisch Medisch Centrum

Meibergdreef 9
1105 AZ 1105AZ
NL

Scientific

Academisch Medisch Centrum

Meibergdreef 9
1105 AZ 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)

Elderly (65 years and older)

Inclusion criteria

- aged 18 years or older;
- diagnosed with a hematological malignancy;
- treatment is expected to result in prolonged (>7 days) neutropenia ($<0.5 \times 10^9/L$), e.g. induction or consolidation treatment for AML or ALL, a myeloablative allogeneic hematopoietic stem cell transplantation, or a cord blood or haploidentical stem cell transplantation;

Exclusion criteria

- Patients are unable to perform the breathing manoeuvre needed for eNose-analysis of exhaled air

Study design

Design

Study type: Observational invasive

Intervention model: Other

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	10-12-2012
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO	
Date:	19-11-2012
Application type:	First submission
Review commission:	METC Amsterdam UMC
Approved WMO	
Date:	07-06-2013
Application type:	Amendment
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

CCMO

ID

NL41287.018.12