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

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

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|---|---|
| **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 x 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

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# 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 x 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 manouevre needed for eNose-analysis of exhaled air

# Study design

## Design

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| Study type: | Observational invasive |
| Intervention model: | Other |

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

### Recruitment

NL

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

## Ethics review

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| 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 | ID |
| --- | --- |
| CCMO | NL41287.018.12 |