the Application of an Electronic Nose in the Early detection of ASpergillosis

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to establish the accuracy with which the eNose can discriminate patients with invasive pulmonary aspergillosis from controls

Ethical review	Approved WMO
Status	Pending
Health condition type	Haematological disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON33126

Source
ToetsingOnline

Brief title
the AENEAS study

Condition

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

Synonym
fungal pneumonia, invasive pulmonary mycosis

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, electronic nose, neutropenia

Outcome measures

Primary outcome

To establish the accuracy with which the Cyranose* can discriminate patients with probable or proven invasive pulmonary aspergillosis from neutropenic controls with fever.

Secondary outcome

To establish whether neutropenic patients with fever but no sign of aspergillosis can be discriminated from healthy subjects, thus measuring the combined influence of chemotherapy, neutropenia, antibiotics and fever on the algorithm used for the main objective.

Study description

Background summary

One of the most difficult forms of pneumonia as to the isolation of the responsible pathogen is invasive pulmonary mycosis. This is reflected by the extensive criteria for *possible*, *probable* and *proven* invasive fungal disease, drafted by the EORTC/MSG. Usually a *probable* infection is considered enough evidence to *establish diagnosis*, as *proven* disease - for which it is required to isolate the responsible pathogen from a specimen obtained from a normally sterile site - is generally only diagnosed post-mortem. In daily practice this diagnostic inaccuracy is quite a problem. The treatment of invasive fungal disease takes a long time (at least 6 weeks) and makes use of antimycotics that can have serious adverse effects, e.g. renal insufficiency, liver failure and bone marrow suppression. Moreover, an invasive fungal infection can delay an oncologically important follow-up treatment. It is therefore clear that more accurate diagnostic methods are highly needed.

In conclusion, the eNose could be a fast, cheap, non-invasive, and easy-to-perform new tool in the diagnosis of pulmonary invasive mycosis that

could improve diagnostic accuracy and possibly obviate broncho-alveolar lavage. It can be incorporated in a pre-emptive strategy and in this way hopefully reduce the mortality of the infectious complications associated with the treatment of haematological diseases.

Study objective

to establish the accuracy with which the eNose can discriminate patients with invasive pulmonary aspergillosis from controls

Study design

All patients will be managed identically and according to local protocol with respect to the prevention, diagnosis and treatment of mycoses. Except for analysis of exhaled air using the eNose every prophylactic, diagnostic and treatment-related procedure is considered to be standard care.

Study burden and risks

Analysis of exhaled air is non-invasive, easy and not associated with any complications or toxicity. The measurement will take 10 minutes. During this period the patient has to breathe through a device. Except for analysis of exhaled air using the eNose, patients included in this trial will not undergo any prophylactic, diagnostic or treatment-related procedure for the purposes of this study other than standard care.

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 that
1. are 18 years of age or older
2. will undergo treatment for a hematological malignancy expected to result in grade 4 neutropenia (according to CTCAE 3.0, i.e. <0.5 x 109 neutrophils/L) of prolonged duration (i.e., more than 7 days), e.g. hematopoietic stem cell transplantation or induction/consolidation treatment for acute myeloid leukaemia
3. have given written informed consent

Exclusion criteria

1. a previously diagnosed invasive mycosis, or
2. the inability to perform the breathing manoeuvre needed for eNose-analysis of exhaled air

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2009
Enrollment:	80
Type:	Anticipated

Ethics review

Approved WMO

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	NL29180.018.09