The AENEAS study: the Application of an Electronic Nose in the Early detection of ASpergillosis.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON23757

Source
Nationaal Trial Register

Brief title
the AENEAS study

Health condition

invasive pulmonary aspergillosis

Sponsors and support

Primary sponsor: AMC, Amsterdam
Source(s) of monetary or material Support: AMC, Amsterdam

Intervention

Outcome measures

Primary outcome

The accuracy with which an eNose can discriminate between patients with probable or proven invasive pulmonary aspergillosis and neutropenic controls with fever, as measured by the cross-validated values of the sensitivity, specificity and accuracy of the predictive

algorithm.

Secondary outcome

The accuracy in discriminating neutropenic controls with fever from healthy volunteers using the algorithm derived for the primary endpoint, as measured by the cross-validated values of the sensitivity, specificity and accuracy of the predictive algorithm.

Study description

Background summary

Introduction

There is a need for new diagnostic methods to facilitate earlier diagnosis and treatment of invasive pulmonary mycosis (IPM) during prolonged chemotherapy-induced neutropenia (PCIN). Exhaled breath analysis could fulfill this need.

Objective

Before studying serial samples during neutropenia, we will first establish the accuracy of exhaled breath analysis to discriminate patients with invasive pulmonary aspergillosis (IPA), the most frequent cause of IPM, from neutropenic controls with fever.

Study design

Single center study with a prospective cohort design. Patients will be sampled once.

Population

Patients that will undergo treatment for a hematological malignancy expected to result in grade 4 neutropenia for more than 7 days (PCIN).

Cases: Patients with probable or proven IPA and a positive galactomannan assay on bronchoalveolar lavage (BAL).

Controls: Patients with fever but no possible, probable or proven IPM and no positive galactomannan assay performed on serum and BAL.

Diagnostic intervention

Exhaled breath analysis using an electronic nose (eNose) and gas chromatography-mass spectrometry
(GC-MS). GC-MS will be used to unravel the molecular mechanisms by which the eNose detects aspergillosis.

Primary endpoint

The accuracy with which an eNose can discriminate between cases and controls as measured by the
cross-validated accuracy of the predictive algorithm. Raw data are analysed by discriminant analysis on principal component reduction after which the results will be validated using the “leave-one-out” method.

Sample size

Our aim is to include 125 neutropenic episodes in 80 patients resulting in 10 cases and 10 controls.

Time line

Accrual will take an estimated 18 months, data analysis and writing the publication 6 months. During the accrual we will in parallel perform additional research in vitro and in CF patients for our GC-MS analyses.

Economic evaluation

A limited economic evaluation will be performed by modelling the diagnosis of IPA using a decision tree. The cost and accuracy of various combinations of diagnostic procedures will be determined. We will establish whether the addition of the eNose to the non-invasive work-up of suspected IPA obviates BAL without a loss in health.

Study objective

N/A

Study design

N/A

Intervention

Exhaled breath analysis using an electronic nose and gas chromatography-mass spectometry.

Contacts

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Eligibility criteria

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.

If the neutropenic episode is part of a sequence of prolonged neutropenias, the informed consent will apply to all neutropenic episodes. The moment anti-mold treatment is started, the patient will go off-protocol after analysis of exhaled air using the eNose.

Exclusion criteria

1. A previously diagnosed invasive mycosis;

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:	Parallel
Allocation:	N/A: single arm study
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2010
Enrollment:	90
Type:	Anticipated

Ethics review

Positive opinion

Date:	16-01-2010
Application type:	First submission

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	NL2060
NTR-old	NTR2177
Other	AENEAS : 09/212
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A