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

Gepubliceerd: 16-01-2010 Laatst bijgewerkt: 18-08-2022

N/A

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON23757

Bron
NTR

Verkorte titel
the AENEAS study

Aandoening

invasive pulmonary aspergillosis

Ondersteuning

Primaire sponsor: AMC, Amsterdam
Overige ondersteuning: AMC, Amsterdam

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

N/A

Onderzoeksopzet

N/A

Onderzoeksproduct en/of interventie

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

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. A previously diagnosed invasive mycosis;

2. The inability to perform the breathing manoeuvre needed for eNose-analysis of exhaled air.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-10-2010
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	16-01-2010
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL2060
NTR-old	NTR2177
Ander register	AENEAS : 09/212
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A