the Application of Exhaled breath aNalysis in the Early detection of ASpergillosis

Published: 15-02-2021
Last updated: 04-06-2024

To determine the accuracy with which patients with probable or proven invasive pulmonary aspergillosis and neutropenic controls can be discriminated from each other, as measured by the values of the sensitivity, specificity and accuracy.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON55217

Source
ToetsingOnline

Brief title
the AENEAS-3 study

Condition

- Hepatobiliary neoplasms malignant and unspecified

Synonym
invasive 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: exhaled breath analysis, invasive aspergillosis

Outcome measures

Primary outcome

The sensitivity, specificity and accuracy.

Secondary outcome

n.a.

Study description

Background summary

We hypothesize that invasive pulmonary aspergillosis can be diagnosed through exhaled biomarkers. The objective of this exploratory study is to identify these biomarkers by analyzing exhaled breath of patients with and without invasive pulmonary aspergillosis. Putative biomarkers will be studied in a larger follow-up study or will be used to fine-tune an eNose device.

Study objective

To determine the accuracy with which patients with probable or proven invasive pulmonary aspergillosis and neutropenic controls can be discriminated from each other, as measured by the values of the sensitivity, specificity and accuracy.

Study design

Single center pilot study, prospective cohort.

Study burden and risks

A sample of exhaled breath and a throat and nose swab will be taken from each patient.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL
Scientific
Academisch Medisch Centrum

Meibergdreef 9
Amsterdam 1105AZ
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patient population: patients, aged 18 or older, that will undergo treatment for a hematological malignancy expected to result in grade 4 neutropenia for more than 7 days, e.g. hematopoietic stem cell transplantation or induction/consolidation treatment for acute myeloid leukaemia.

Exclusion criteria

Eerder doorgemaakte invasieve mycose.

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:	Recruiting
Start date (anticipated):	08-09-2021
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Date:	15-02-2021
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	NL74649.018.20