Advanced Early Detection of airway pathogens in children and adults with Cystic Fibrosis during routine follow-up and exacerbation.

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Primary Objective: To investigate the yield of two methods of exhaled breath analysis (PCR based and VOC based) in the detection of Pseudomonas aeruginosa colonization or infection in young patients with cystic fibrosis (CF).Secondary Objective(s):…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON52071

Source
ToetsingOnline

Brief title
AED-CF

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym
CF and pseudomonas aeroginosa

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: CF, exhaled air, Mucosal lining fluid (MLF), pseudomonas aeroginosa

Outcome measures

Primary outcome

Bacterial culture results for Pseudomonas aeruginosa in cough swab or sputum.

PCR result for Pseudomonas aeruginosa in MBS sample.

VOC profile compatibility with Pseudomonas aeruginosa colonization / infection.

Pseudomonas aeruginosa antibodies detected in serum and mucosal lining fluid.

Detection of Pseudomonas aeruginosa in recirculating tissue macrophages by

TiMaSCAN

Leeds criteria for Pseudomonas aeruginosa infection at time of study visit.

Secondary outcome

Patient experience of exhaled breath sampling.

Study description

Background summary

With this study we would like to investigate the potential of new, innovative ways of detecting Pseudomonas aeruginosa in patients with cystic fibrosis (CF) during and outside of exacerbations. We will use two ways of exhaled breath analysis: a polymerase chain reaction (PCR) based technique with the Modular Breath Sampler (MBS) and a targeted volatile organic components (VOC) analysis. Next to exhaled breath, we will analyze mucosal lining fluid (MLF) for the presence of antibodies against Pseudomonas. Results of these techniques will be compared to the traditional bacterial cultures done with coughswabs, sputum culture or broncho alveolar lavage (BAL). Patients will be categorized for

Pseudomonas status according to the Leeds criteria. The potential of the new techniques in early detection of Pseudomonas will be investigated.

Study objective

Primary Objective:
To investigate the yield of two methods of exhaled breath analysis (PCR based and VOC based) in the detection of Pseudomonas aeruginosa colonization or infection in young patients with cystic fibrosis (CF).

Secondary Objective(s):
In view of the detection of Pseudomonas aeruginosa in young patients with CF:
to correlate the results of two methods of exhaled breath analysis with the current *gold standard* of diagnostics: bacterial culture and serology.
To analyze / model the additive value of innovative diagnostics like exhaled breath analysis and mucosal lining fluid analysis in the early detection of Pseudomonas aeruginosa in young patients with CF.

Study design

This will be an explorative multicentre cross-sectional prospective study among young patients with CF that will be seen in the Radboudumc or MUMC+, during their routine (uniform) check-up and during exacerbations during the period of September 2021- until December of 2022. A group of elective patients undergoing a BAL will be included as control subjects for the breath samples.

Study burden and risks

The burden associated with participation, will be 30 minutes that are asked from the patient. In these 30 minutes, additional information will be given, Informed Consent will be signed and two different breath samples will be collected. There will also be a mucosal lining fluid (MLF nose strip) sample collected and an additional blood sample will be collected during regular labwork (therefore not forming a higher risk for complications, compared to the regular check-up that is taking place). In the past, the MBS and VOC samples have been considered *not WMO mandatory* by the MREC.
There are no extra risks for the study participant. All the samples that are needed, will be collected just once and it will all be on the same day. No additional physical examination will be needed.
Most patients with CF will develop Pseudomonas aeruginosa colonization / infection during childhood or early adulthood. Therefore the young CF patients form a unique population and this study cannot be performed in adults only.

For the controlgroup this will be only 2 breath samples, this will take about 20 minutes.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)

Inclusion criteria

- Patient must be diagnosed with CF and above the age of 5 years old at the moment of inclusion.
- Patients will be included during a routine visit (n = 70) and can participate only once during this visit. Some patients will be included during a hospital visit because of an exacerbation or a Broncho Alveolar Lavage (BAL) visit (N = 35). This means it is possible that the same patient participates twice. One time as a routine check-up and one time (with a different study number) as an exacerbation or BAL visit.
- To be able to participate, at least one breath sample is mandatory to participate. It is preferable to only include patients that are intending to

participate in all elements so that all (4) categories will be well represented.

(The control group will consist of patients having an elective broncho alveolar lavage, or patients with CF or conditions that increase the risk of Pseudomonas aeroginosa infection like extensie bronchiectasis, chronic lung disease will not be included). The controle group will be above the age of 5 years old.

Exclusion criteria

A patient with serious tachypnea or dyspnea, oxygen need or a patient who is physically not able to participate, will be excluded from participation in this study.

Study design

Design

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

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	14-03-2022
Enrollment:	144
Type:	Actual

Ethics review

Approved WMO

Date:	02-02-2022
Application type:	First submission

Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-04-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	01-03-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	17-07-2023
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL79103.091.21