

Early detection of exacerbations in mucociliary clearance diseases.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON26275

Source

NTR

Health condition

Cystic Fibrosis
Primary Ciliary Dyskinesia

Sponsors and support

Primary sponsor: Dept. Respiratory Medicine
Academic Medical Centre, University of Amsterdam

Source(s) of monetary or material Support: Merieux Institute

Intervention

Outcome measures

Primary outcome

1. Relative changes in electronic nose sensors;
2. Retention time;
3. Abundance and mass to charge ratio from GC-MS analysis.

Secondary outcome

(Change in) bacterial and viral diversity.

Study description

Background summary

N/A

Study objective

N/A

Study design

3 monthly collection of study samples and during an exacerbation.

Intervention

Longitudinal observational study during one year with collection of 5 exhaled breath and microbiology samples.

Contacts

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Eligibility criteria

Inclusion criteria

1. CF diagnosis is based on: clinical symptoms in combination with an abnormal sweat test (chloride > 60 mmol/l) and/or identification of mutations in both alleles of the CFTR gene;
2. PCD diagnosis is based on: A combination of clinical symptoms, abnormal movement of cilia on microscopic evaluation of respiratory epithelial biopsies and epithelial cell cultures, or identification of an ultra structural defect in the cilia by electron microscopy;
3. ≥ 6 years of age;
4. Stable respiratory disease for at least 6 weeks (as determined by the treating physician);
5. Ability to perform lung function measurement.

Exclusion criteria

1. Mental retardation;
2. Diabetes Mellitus (CF complication);
3. Technical unsatisfactory performance of measurements;
4. On the waiting list for lung transplantation;
5. Participation in the PREVEC or VERTEX study (AMC).

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	01-11-2012
Enrollment:	100
Type:	Anticipated

Ethics review

Not applicable	
Application type:	Not applicable

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	NL3464
NTR-old	NTR3616
Other	:
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results

N/A