Pilot study: Respiratory microbiome analysis by the IS-pro technology

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON44188

Source
ToetsingOnline

Brief title
The Maastricht Respiratory Microbiome Study

Condition

- Respiratory disorders NEC

Synonym
community of microorganisms, microbiome

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: Microbiome Ltd. & IS Diagnostics

Intervention

Keyword: IS-pro technology, Respiratory microbiome, Sample types

Outcome measures

Primary outcome

To determine the optimal sample type for respiratory microbiome analysis using the IS-pro technology.

Secondary outcome

- Intra-patient analysis to define and compare the respiratory microbiome and its microbial diversity by BAL fluid, bronchial aspirate, induced sputum samples, throat and nose swabs;

- Longitudinal analysis of respiratory microbiome in sputum, throat and nose swabs, to assess the respiratory microbiome and the microbial diversity of patients over time, between the same and different sample types.

Study description

Background summary

For a long time, it was believed that the lungs of healthy individuals were sterile. More recently, it was shown that the lungs of both healthy individuals and diseased patients consisted of a rich respiratory microbiome, even in the absence of symptoms of an infection. If this community of micro-organisms differs between healthy individuals and patients with a lung disease has not been sufficiently studied. Moreover, it's unknown which role these micro-organisms play in patients with lung diseases.

Study objective

Different sampling methods have been used for respiratory microbiome analyses, including both invasive as well as non-invasive techniques. We would like to investigate if the results of the bronchoscopy are comparable with results from the nose swab, throat swab or sputum sample, which are much easier sampling

methods. In addition, different technologies were applied, with the interspace-region-based profiling (IS-pro) method as a new technology tested on the intestinal microbiome. Until now, no lung samples have been tested by the IS-pro technology, although this technology has some advantages over next-generation sequencing. Research showed that IS-profiling is highly reproducible, fast and easy to perform and suitable for high-throughput profiling of the human intestinal microbiome. Therefore, the IS-pro technology is more readily adoptable to routine diagnostics compared to next-generation sequencing.

Study design

Pilot study

Study burden and risks

All individuals are planned for bronchoscopy. The extra procedure of a mini-BAL will not result in additional risks. The throat swab can give a gag reflex.
Risks associated with collecting induced sputum are bronchospastic reaction, dyspnoea, vomiting, fear and cough. For this procedure, lung function is necessary, which can result in cough, dizziness and hyperventilation. However, these procedures are carried out under the supervision of experienced staff and adjusted or stopped if necessary. Generally speaking, there is a low risk of participating in this pilot study, as the potential risks are temporary.

Individuals are asked to come one and a half hour before bronchoscopy, for sampling the throat and sputum. This is the same for the follow-up measures.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

* Diagnosis of COPD stages I-IV, class A-D, as defined by the Global initiative for chronic Obstructive Lung Disease (GOLD);
* Patients must be planned to undergo a bronchoscopy;
* Patients must be able to complete questionnaires;
* Patients must sign and date an informed consent prior to inclusion.

Exclusion criteria

* Chronic use of oral corticosteroids > 10 mg/day;
* Investigator*s uncertainty about the willingness or ability of the patient to comply with the protocol requirements, e.g. not smoking 6 hours before and fasting two hours before sputum induction;
* Patients with mental conditions rendering them unable to understand the nature, scope, and possible consequences of the study;
* Patients unlikely to comply with the protocol, e.g. uncooperative attitude, and unlikelihood of completing the study (not able to attend all three visits).

Study design

Design

Study type: Observational invasive
Masking: Open (masking not used)

Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2015
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	08-04-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 19937
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49157.068.14
Other	Onderzoek wordt geregistreerd zodra goedkeuring is ontvangen (op www.trialregister.nl)
OMON	NL-OMON19937

Study results

Date completed:	17-01-2017
Actual enrolment:	21