Published: 20-08-2015
Last updated: 13-12-2022

It is expected that the respiratory microbiome will be relatively stable over time in non-infectious patients.

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|---|---|
| **Ethical review** | Approved |
| **Status** | Completed |
| **Health condition type** | - |
| **Study type** | Observational non invasive |

# Summary

## Brief title

Maastricht Respiratory Microbiome Study (MRMS)

## Health condition

COPD, bacteria, viruses

COPD, bacteriën, virussen

## Sponsors and support

| | |
|---|---|
| Primary sponsor : | azM |
| Source(s) of monetary or material Support : | Microbiome Ltd. & IS Diagnostics |

## Intervention

## Outcome measures

## Primary outcome

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

### Secondary outcome

1. 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;
2. 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

The human microbiome has gained interest in health and disease. 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. Until now, different sampling methods have been used for respiratory microbiome analyses, including both invasive as well as non-invasive techniques. 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 objective

It is expected that the respiratory microbiome will be relatively stable over time in non-infectious patients.

### Study design

Baseline (visit 1)
Visit 2 (1/2 weeks after visit 1)
Visit 3 (half year after visit 1)

### Intervention

Nose swab
Throat swab
Sputum
Bronchial aspirate
Mini-BAL

## Contacts

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## Eligibility criteria

### Inclusion criteria

In order to be eligible to participate in the study, a patient must meet all of the following criteria:
• Diagnosis of COPD stages I-IV, class A-D, as defined by the Global initiative for chronic Obstructive Lung Disease (GOLD)23;
• 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

A patient who meets any of the following criteria will be excluded from participation in this study:
• Chronic use of oral corticosteroids > 10 mg/day;
• Investigator’s uncertainty about the willingness or ability of the subject 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 non invasive |
| Intervention model : | Other |
| Masking : | Open (masking not used) |
| No intervention arm : | N/A , unknown |

## Recruitment

NL

| | |
|---|---|
| Recruitment status : | Completed |
| Start date (anticipated) : | 24-08-2015 |
| Enrollment : | 20 |
| Type : | Actual |

# Ethics review

Approved

| | |
|---|---|
| Date : | 20-08-2015 |
| Application type : | First submission |

# Study registrations

## (Historical) registrations known in this register

No registrations found

## In other registers

Source : NTR

| Register | ID |
|---|---|
| NTR-new | NL5220 |
| NTR-old | NTR5369 |
| CCMO | NL49157.068.14 |

# Study results