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

Gepubliceerd: 20-08-2015 Laatst bijgewerkt: 15-05-2024

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

Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON19937

Bron
Nationaal Trial Register

Verkorte titel
Maastricht Respiratory Microbiome Study (MRMS)

Aandoening

COPD, bacteria, viruses

COPD, bacteriën, virussen

Ondersteuning

Primaire sponsor: azM
Overige ondersteuning: Microbiome Ltd. & IS Diagnostics

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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

technology.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Baseline (visit 1)

Visit 2 (1/2 weeks after visit 1)

Visit 3 (half year after visit 1)

Onderzoeksproduct en/of interventie

Nose swab

Throat swab

Sputum

Bronchial aspirate

Mini-BAL

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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).

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	24-08-2015
Aantal proefpersonen:	20
Type:	Werkelijke startdatum

Ethische beoordeling

Positief advies

Datum:	20-08-2015
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44188
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5220
NTR-old	NTR5369
CCMO	NL49157.068.14
OMON	NL-OMON44188

Resultaten