Respiratory microbiome and clinical data analysis for the prediction of acute exacerbations in COPD

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A novel approach/algorithm for individualised risk assessment of COPD exacerbations, which integrates both microbiological data and clinical information, improves the accuracy of exacerbation prediction in COPD patients over methods based on...

Ethische beoordeling	Niet van toepassing
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON26474

Bron
NTR

Verkorte titel
REDALERT

Aandoening

COPD

Ondersteuning

Primaire sponsor: None
Overige ondersteuning: Eurostars (E! 113530, (consortium) / RVO

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Accuracy of risk assessment for the prediction of acute exacerbations of COPD based on microbiological and clinical analyses.

Toelichting onderzoek

Achtergrond van het onderzoek

COPD is a devastating disease for which no curative treatments are available. Global prevalence of COPD is estimated at 12% and is expected to rise over the next decades, due to increasing smoking behavior in developing countries and aging populations in high-income countries. The clinical course of COPD is characterized by exacerbations, acute worsening of symptoms. Exacerbations incur extreme costs to society due to the need for acute treatment and hospitalisation. Finally, exacerbations play a crucial role in the progression of lung function deterioration. About 10% of patients hospitalized with exacerbation will not survive, while another 15% will not survive beyond 1 year.

Prevention of exacerbations is one of the key aims of COPD treatment but is largely ineffective. Insufficient understanding of the pathobiology and heterogeneity of these events and lack of validated biomarkers to predict and optimize treatment of exacerbations contribute to this tremendous unmet need. The onset of exacerbations was recently shown to coincide with a shift in the respiratory tract microbiota (RTM). Regular monitoring of the RTM in exacerbation prone COPD patients thus represents an opportunity to predict exacerbation occurrence earlier. This enables clinicians to initiate appropriate therapies to prevent exacerbations.

An easy-to-use technique for the analysis of the RTM in daily clinical practice will enable appropriate therapy early on and reduce the risk of life-threatening exacerbations. REDALERT’s goal is to combine the ISPro technology and geneXplain platform to develop an integrated solution for routine RTM analysis with:
A) novel processing methods for ISPro to accurately characterize the RTM and the relative abundance and shifts therein of microbiota
B) clinical decision-making algorithms based on the geneXplain platform to predict exacerbations from RTM samples and associated clinical patient data
C) integration with two main hospital information systems to include additional patient health data.

Doel van het onderzoek

A novel approach/algorithm for individualised risk assessment of COPD exacerbations, which integrates both microbiological data and clinical information, improves the accuracy of exacerbation prediction in COPD patients over methods based on clinical parameters alone.

Onderzoeksopzet

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Age ≥ 18 years
• Written informed consent
• Physician-confirmed diagnosis of COPD (spirometry) (FEV1≤ 80% predicted)
• Smoking history: Min. 10 packyears

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Inability to understand the nature, scope, and possible consequences of the study
• Life expectancy of less than 12 months
• Newly diagnosed active pulmonary tuberculosis within the last 12 months • Unstable cardiopulmonary or metabolic co-morbidities
• Macrolide maintenance treatment

Onderzoeksopzet

Opzet

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

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-09-2021
Aantal proefpersonen:	300
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Toelichting
IPD will be shared. Alphanumerical pseudonyms will be given per study site consisting of a study acronym (RA_C), the study site (e.g. MUMC) and a consecutive number. Re-identification lists will be maintained locally at the study centres. They will be stored electronically and password-protected on clinic servers, with access restricted to study team members of the respective site. Re-identification lists will be stored separately from study data. All study data will be stored using the participants' pseudonym. Study visits are documented as research case in the sites' hospital information system. Clinical data collected for the project are transferred to (e)CRFs (SecuTrial) using the participant's pseudonym. Pseudonymised data can be transferred by the study centre to the project partners listed in the study protocol. Identifying data, including name or contact details, will not be transferred. Data will not be transferred to third parties outside the project consortium. Data will only be published anonymised.

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL9801
Ander register	METC azM/UM : METC azM/UM 068

Resultaten