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

No registrations found.

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

Summary

ID

NL-OMON26474

Source
NTR

Brief title
REDALERT

Health condition

COPD

Sponsors and support

Primary sponsor: None
Source(s) of monetary or material Support: Eurostars (E! 113530, (consortium) / RVO

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• Composition of the respiratory microbiota in patients with COPD and relation to exacerbation history and clinical parameters
• Compositional clustering of respiratory microbiota in relation to disease phenotype
• Stability of the respiratory microbiota in patients with COPD in the stable phase, during exacerbation and recovery
• Host gene signatures in relation to respiratory microbiota profile

Study description

Background summary

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.

Study objective

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.

Study design

9

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

• 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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-09-2021
Enrollment:	300
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Yes

Plan description
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.

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	NL9801
Other	METC azM/UM : METC azM/UM 068

Study results