Biological Investigation of Explanted Endobronchial Lung Valves study

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The main objective of this study is to study and understand the underlying biological principles of granulation and fibrotic responses limiting the effectiveness and longevity of ELVR treatment with EBVs.

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

Summary

ID

NL-OMON50009

Source
ToetsingOnline

Brief title
BIO-EXEL study

Condition

- Respiratory disorders NEC

Synonym
Granulation tissue after endobronchial valve treatment

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: emphysema, endobronchial valves, endoscopic lung volume reduction, granulation tissue

Outcome measures

Primary outcome

The BIO-EXEL study is an observational study to investigate the biological mechanisms underlying the adverse granulation and fibrotic responses upon treatment with endobronchial lung valves. Therefore, the primary outcomes encompassment biological measurements indicating susceptibility for these adverse effects, including soluble factors (serum, bronchial wash biomarkers), genetic factors, and histological factors. Primary study parameters further include factors elaborating the underlying biological mechanisms of these adverse effects, including the presence of specific cell-types at the site of granulation and fibrotic responses, the presence of specific protein and biofilm signatures on the explanted endobronchial lung valves.

Secondary outcome

not applicable

Study description

Background summary

COPD is a severe, often progressive and currently incurable lung disease which affects both the upper airways (chronic bronchitis) as well as the lower airways (emphysema). In advanced stages of the disease air-trapping severely reduces the ability to breathe and subsequently the quality of life. A highly effective treatment for restoring lung mechanical functionality of these patients is the introduction of bronchoscopic lung volume reduction, e.g. implanting small silicone/nitinol valves inside the airways to reduce

air-trapping. Although successfully investigated in a selected group of severe COPD patients, the effectiveness of the treatment was in most patients short-lived due to fibrotic and granulation responses and tissue-material interactions.

Study objective

The main objective of this study is to study and understand the underlying biological principles of granulation and fibrotic responses limiting the effectiveness and longevity of ELVR treatment with EBVs.

Study design

150 consequtive severe COPD patients getting endobronchial lung valves in the context of regular care, will be enrolled within the study in order to collect biological materials. Prior to and during the bronchoscopic procedure samples will be collected. Patients who are re-hospitalized and in need for valve replacement or removal within a time-period of 18 months are asked to provide a second set of samples during the standard bronchoscopy (estimated n=20-30). Eighteen months after enrolment, 20 patients who did not experience any problems with the endobronchial valves will be invited to the hospital for a bronchoscopic treatment during which a set of samples will be collected.

Study burden and risks

No additional study related interventions besides the collection of samples will be applied to the patients, with the exception of the complaint-free group which will receive one additional bronchoscopic intervention. The bronchoscopic treatments which are in the context of regular care are increased in length by approximately 10 minutes upon enrollment within the BIO-EXEL study. The collection of biological materials are routinely performed and have been proven risk-free so far. No further risks are associated with this study.

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

Patients with severe emphysema who undergo an endoscopic lung volume reduction treatment with endobronchial valves

Written informed consent.

Exclusion criteria

Anticoagulation which cannot be stopped

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	15-03-2021
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO

Date:	20-05-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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
CCMO	NL72533.042.20