Change in task-related oxygen uptake after bronchoscopic lung volume reduction with endobronchial valves

Published: 31-03-2025
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To investigate the change in exercise physiology during daily activities after EBV treatment.

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

Summary

ID

NL-OMON57414

Source
ToetsingOnline

Brief title
Crocodile study

Condition

- Respiratory disorders NEC

Synonym
COPD

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: COPD, Daily activities, Exercise capacity, Lung volume reduction

Outcome measures

Primary outcome

The change in task-related oxygen uptake measured with a mobile oxygen device during activities of daily life 6 months after EBV treatment.

Secondary outcome

To investigate the change between baseline and 6 months of follow-up after EBV treatment in:

- task completion time.

- ventilation during rest.

- ventilation during activities of daily life.

- dyspnoea sensation during activities of daily life

- oxygen saturation during activities of daily life

- diaphragmatic neuromechanical coupling during rest and activities of daily life

- dynamic hyperinflation during activities of daily life

- oxygen pulse during activities of daily life.

- ventilatory efficiency during activities of daily life

Study description

Background summary

Bronchoscopic lung volume reduction using endobronchial valves (EBV) has emerged as a viable treatment option for eligible patients with severe

emphysema. In all studies conducted so far, exercise capacity has only been measured using the 6-minute walk distance test (6MWT). The 6MWT is conducted under laboratory conditions, which weakly correspond to activities of daily living (ADL). It is known that patients with COPD frequently experience problems during ADL, which can lead to avoidance of or care dependency for performing certain tasks and have a significant social impact on their lives. Patients report that it is easier to perform ADLs after EBV treatment. We also found that it was easier for patient to perform these activities after the EBV treatment. However, we did not investigate the physiological load during these ADLs. This could be measured with a mobile oxygen device which can measure oxygen uptake (VO2) and carbon dioxide production (VCO2) under more functional conditions and thus measure the metabolic load of these activities. Potentially, EBV treatment could improve the metabolic load and consequently symptom perception, thus enhancing the execution of ADLs, which is an important patient-centred outcome. However, this has not been investigated so far.

Study objective

To investigate the change in exercise physiology during daily activities after EBV treatment.

Study design

Observational study in which the study population will be asked to perform some additional test during regular visits for the bronchoscopic lung volume reduction treatment with valves.

Study burden and risks

This study has no specific benefits for the participating patients and the study also has no major risks.

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

1) Patient is scheduled for a bronchoscopic lung volume treatment using Pulmonx Zephyr
Endobronchial Valves;
2) Patient read, understood and signed the Informed Consent Form.

Exclusion criteria

1) De patiënt staat gepland voor een bronchoscopische longvolumebehandeling met behulp van Pulmonx Zephyr endobronchiale kleppen.
2) De patiënt heeft het toestemmingsformulier gelezen, begrepen en ondertekend.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO

Date:	31-03-2025
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
ClinicalTrials.gov	NCT06702072
CCMO	NL88372.042.24