Assessing the diaphragm before and after Endobronchial Valve Treatment

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To investigate the change in diaphragm function after bronchoscopic lung volume reduction treatment with endobronchial valves (EBV).

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

Summary

ID

NL-OMON52012

Source
ToetsingOnline

Brief title
DIAMANT-study

Condition

- Respiratory disorders NEC

Synonym
COPD emphysema

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, Diaphragm, Lung volume reduction, Respiratory muscles

Outcome measures

Primary outcome

Change in diaphragm function 6 week after EBV treatment measured by ultrasound. The main outcome will be diaphragm motion (difference between maximum in- and expiration).

Secondary outcome

• Change in diaphragm function 6 week after EBV treatment measured by ultrasound (other ultarsound outcomes than the main outcome).

• Change in diaphragm function 3 days after EBV treatment measured by ultrasound.

• Change in diaphragm function 6 weeks after EBV treatment measured by quantified CT-analysis.

• Change in diaphragm function 6 weeks after EBV treatment measured by EMG.

• Change in respiratory muscle function 6 weeks after EBV treatment measured by ultrasound.

• Change in respiratory muscle function 6 weeks after EBV treatment measured by EMG.

• Change in respiratory muscle function 6 weeks after EBV treatment measured by MIP/MEP.

• Change in skeletal muscle function 6 weeks after EBV treatment measured by ultrasound.

• Change in skeletal muscle function 6 months after EBV treatment measured by ultrasound.

• Change in exercise capacity 6 weeks after EBV treatment measured by 6MWD and 30STS.

• Change in exercise capacity 6 months after EBV treatment measured by 6MWD and 30STS.

• Change in ventilation distribution of the lungs 6 weeks after EBV treatment measured using XV Lung Ventilation Analysis Software (XV LVAS).

• Association between change in diaphragm function and change in lung hyperinflation measured by bodyplethysmography or CT-scans.

• Association between change in diaphragm function and change in respiratory muscle function measured by EMG or ultrasound.

• Association between change in diaphragm function and change dyspnea severity.

• Association between change in diaphragm function and change in level of fatigue.

• Association between change in diaphragm function and skeletal muscle function.

• Association between change in diaphragm function and exercise capacity.

• Association between change in diaphragm function and change in ventilation distribution.

Study description

Background summary

The diaphragm is the principal respiratory muscle, which separates the thorax from the abdomen. Hyperinflation of the lung places the diaphragm at a mechanical disadvantage, shortens its operating length and changes the mechanical arrangement of costal and crural components of the diaphragm and consequently decrease the tension that can be developed and the amount of transdiaphragmatic pressure that can be produced. Reducing the lung

hyperinflation could improve the diaphragm function mechanically. One of the treatments to reduce lung hyperinflation is the bronchoscopic treatment using endobronchial valves. To our knowledge the change in diaphragm function after bronchoscopic endobronchial valve treatment has never been investigated.

Study objective

To investigate the change in diaphragm function after bronchoscopic lung volume reduction treatment with endobronchial valves (EBV).

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 one-way valves
2)Patient read, understood and signed the Informed Consent Form

Exclusion criteria

There are no exclusion criteria for this study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	23-01-2023
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	24-05-2021
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	13-04-2022
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	25-01-2023
Application type:	Amendment
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	NCT04735731
CCMO	NL76676.042.21