Measuring collateral ventilation using Chartis® to select patients with severe emphysema for endobronchial valve treatment: conscious sedation versus general anesthesia

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In this project we want to investigate whether there is a difference in Chartis measurement outcomes between these two methods of anesthesia: conscious sedation and general anesthesia.

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

Summary

ID

NL-OMON46522

Source
ToetsingOnline

Brief title
CONTEST

Condition

- Respiratory disorders NEC

Synonym
Emphysema, Lung disease

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: Anesthesia, Bronchoscopy, Collateral Ventilation, Emphysema

Outcome measures

Primary outcome

Primary Objective:

1. To compare the duration of Chartis measurement in patients undergoing conscious sedation versus general anesthesia.

Secondary outcome

Secondary Objectives:

2. The failure rate of the Chartis collateral ventilation measurement under general anesthesia versus conscious sedation

3. To investigate qualitative assessment feasibility for the physician in patients undergoing conscious sedation or general anesthesia.

4. To investigate the influence of severity of disease in patients undergoing conscious sedation or general anesthesia.

5. To investigate outcome difference in collateral ventilation status in patients undergoing conscious sedation versus general anesthesia

Study description

Background summary

The Chartis® (Pulmonx, CA, USA) measurement system is a tool to assess interlobar collateral ventilation during bronchoscopy. Assessing collateral ventilation is important when you intend to treat a patient with endobronchial valves. Chartis measurement of collateral ventilation can be performed under both conscious sedation as well as general anesthesia. There is no consensus on what is the preferred method of anesthesia for Chartis measurements in the literature.

Study objective

In this project we want to investigate whether there is a difference in Chartis measurement outcomes between these two methods of anesthesia: conscious sedation and general anesthesia.

Study design

This study will be a single center observational study

Study burden and risks

Risks associated with our study include the risks associated with an additional Chartis measurement and a longer duration of the bronchoscopy and anesthesia (approximately 15 minutes). There are no additionally scheduled screening, baseline or follow-up visits.

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

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
-Patient is scheduled for a bronchoscopic lung volume treatment using one-way valves
-Patient has provided signed informed consent.

Exclusion criteria

1) FEV1 < 20%
2) RV/TLC>70%
3) pCO2 >6.5
4) RVSP>40mmHg
5) 6MWT<200m
6) Known intolerance to Lidocaine
7) Any other medical reason/condition that warrants a short procedure (physician judgement)

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-04-2018
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	10-10-2017
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

Approved WMO

Date:	11-12-2018
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	NCT03205826
CCMO	NL62374.042.17