A Study of the Use of Chartis* System to Optimize Subject Selection for Endobronchial Lung Volume Reduction (ELVR) in Subjects with Heterogeneous Emphysema

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To evaluate the effectiveness of the Chartis System in selecting subjects with heterogeneous emphysema who will achieve Lung Volume Reduction from Endobronchial Valve therapy.

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

Summary

ID

NL-OMON34198

Source
ToetsingOnline

Brief title
Chartis - BVR study

Condition

- Respiratory disorders NEC

Synonym
COPD Emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Pulmonx, Inc.
Source(s) of monetary or material Support: industrie

Intervention

Keyword: Bronchoscopy, COPD, Lungvolume reduction

Outcome measures

Primary outcome

Use of Chartis subject selection algorithm to select subjects most likely to

experience a minimum of 350mL volume reduction from EBV treatment, as measured

by volumetric CT scan at 30 day follow-up visit.

Secondary outcome

n/a

Study description

Background summary

Patients with end-stage COPD suffer form severe dyspnea and a poor quality of life, with no current effective medical treatment. Only for a very small, highly selective group of COPD patients, very invasive surgical procedures like lung volume reduction surgery (LVRS) or lungtransplantation are available. Recently, a non-surgical bronchoscopic treatment modality called bronchoscopic lungvolume reduction (BVR) using one-way endobronchial valves to achieve lung volume reduction has come available. BVR is highly effective in a subset of patients with COPD, with heterogeneous distributed emphysema with intact intralobular fissures present on CT. However, determining intact intralobular fissures on CT is very difficult. Therefore we intent to use a balloon catheter based system that can assess the presence of collateral ventilation. This assessment of collateral ventilation can significantly increase the succesrate of bronchosopic lungvolume reduction using one-way valves, and will eliminate those patient who otherwise would have been treated.

Study objective

To evaluate the effectiveness of the Chartis System in selecting subjects with heterogeneous emphysema who will achieve Lung Volume Reduction from Endobronchial Valve therapy.

Study design

A non-randomized, multi-center, prospective feasibility study.

Study burden and risks

The patients that will be screened for potential participation will receive pulmonary function testing, thoracic HRCT scanning (both are often already available) and an outpatient visit. The patients that will be included will have to come to our outpatient clinic and perform a 6 min walking test. For the actual treatment an out-patient bronchoscopy with assessment of the collateral flow using the balloon catheter. If, based on the assessment of the collateral flow, the patient is a suitable candidate for bronchoscopic lung volume reduction, a one month follow-up outpatient visit including a HRCT scan, pulmonary function tests, and a 6 min walking test will be performed. The included patients will have to put a reasonable effort in the study, and this seems in balance with the expected outcome. This especially, since the expectation is that we have a number of patients where we previously (as based on the CT scan assessment) made the assumption that they were not good candidates, and vice versa: a number of patients that we previously thought to be good candidates (based on the CT scan), are now not going to be treated. The risk to patients for this study is not greater than the risk that anyone with this disease has on getting side effects of the described investigations (CT, lung function, walking test, bronchoscopy). Of the assessment of the collateral flow using the balloon catheter during bronchoscopy are so far in> 60 patients no side effects described.

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

-Heterogeneous emphysema as determined by physician visual review of standard CT
-Able to obtain Chartis measurement value
-Signed informed consent

Exclusion criteria

-Active pulmonary infection
-FEV1 <15% and > 50% of predicted value
-Any co-existing major medical problems that would not make it possible for the subject to tolerate a bronchoscopic procedure

Study design

Design

Study phase:	2
Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)

Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	04-10-2010
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	30-09-2010
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	NCT01101958
CCMO	NL32606.042.10