Study of the AeriSeal® System for HyPerInflation Reduction in Emphysema (ASPIRE)

Published: 06-08-2012
Last updated: 26-04-2024

Assess physiological, functional, and quality of life responses following AeriSeal System treatment compared control in patients with upper lobe predominant (ULP) heterogeneous emphysema

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

Summary

ID

NL-OMON37128

Source
ToetsingOnline

Brief title
ASPIRE Trial

Condition

- Respiratory disorders NEC

Synonym
COPD, Emphysema

Research involving
Human

Sponsors and support

Primary sponsor: AERIS Therapeutics
Source(s) of monetary or material Support: AERIS Therapeutics

Intervention

Keyword: Bronchoscopy, COPD, Emphysema, Lung Volume Reduction

Outcome measures

Primary outcome

Primary Efficacy Endpoint: FEV1 at 12 months post treatment

Secondary outcome

Secondary Efficacy Endpoints:

1. FEV1: The proportion of patients achieving at least a 12% and 100 mL increase in postbronchodilator FEV1 at 12 months post treatment

2. Upper Lobe Volume by CT Scan: The mean change from baseline in upper lobe volume measured by quantitative CT scan at 12 months post treatment

3. St. George*s Respiratory Questionnaire (SGRQ): The proportion of patients achieving at least a 4U decrease in SGRQ total domain score at 12 months post treatment

4. Medical Research Council Dyspnea (MRCD): The proportion of patients achieving at least a 1U decrease in MRCD score at 12 months post treatment

5. Six Minute Walk Test (6MWT): The mean change from baseline in 6MWT at 12 months post treatment

Study description

Background summary

Current treatment of emphysema (COPD gold III-IV) generally is limited to palliative measures that include supplemental oxygen, bronchodilators, anti-inflammatory drugs and pulmonary rehabilitation or to lung transplantation. A small subset of patients with emphysema might benefit by

lung volume reduction surgery, but this procedure is highly invasive and often results in high morbidity and mortality. A minimally invasive treatment with the potential to improve pulmonary function and reduce dyspnea in patients with homogeneous emphysema would provide meaningful clinical benefit.

Study objective

Assess physiological, functional, and quality of life responses following AeriSeal System treatment compared control in patients with upper lobe predominant (ULP) heterogeneous emphysema

Study design

Open-label, prospective, randomized, parallel arm, controlled, multi-center through 1 year post treatment with uncontrolled long-term follow-up through 5 years post treatment.

Intervention

Bronchoscopic lung volume reduction using the AeriSeal System

Study burden and risks

Risks and Benefits In prior clinical studies, treatment with the AeriSeal System was shown to reduce lung volume and improve lung function and quality of life in advanced emphysema patients with acceptable risk. Acute side effects following treatment have included transient dyspnea (60%), chest pain/discomfort (50%), fever (20%), leukocytosis, (20%) and pulmonary infiltrates (15%). These are self limited or resolve with supportive care. Side effects that have required hospitalization within the first 90 days include COPD exacerbations (5-8%), pneumonia (1-2%), and bronchitis (2-5%). Long-term (>6 months) follow-up has shown no significant late treatment-related complications or emergent safety issues.

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

age >40
advanced upper lobe emphysema on CT
mMRC 2 or higher
6-MWD > 150 m post pulmonary rehab
post BD FEV < 50 % pred.
TLC > 100 % pred.
RV > 150 % pred.
DLco >= 20% and <= 60% pred.
non-smoking 16 weeks prior to study

Exclusion criteria

Body mass index < 15 kg/m2 or > 35 kg/m2
Alpha1-antitrypsin serum level of <80 mg/dL (i.e. < 11 µmol/L) at screening
Female patient pregnant or breast-feeding
Clinically significant asthma, chronic bronchitis, bronchiectasis or, pulmonary hypertension
Three or more COPD exacerbations requiring hospitalization within 1 year of screening or a COPD exacerbation requiring hospitalization within 8 weeks of Screening
Prior lung volume reduction surgery, prior lobectomy or pneumonectomy, prior lung transplantation, prior airway stent placement, prior pleurodesis, or prior endobronchial lung volume reduction therapy of any type
Significant comorbidity that carries prohibitive risks
CT scan: Presence of the following radiologic abnormalities: Unstable pulmonary nodule on

CT scan greater than 1.0 cm in diameter, infiltrate, interstitial lung disease, significant pleural disease, giant bullous disease (> 10 cm)
Requirement for mechanical ventilator support (invasive or non-invasive)

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	20-09-2012
Enrollment:	30
Type:	Actual

Medical products/devices used

Generic name:	The Aeriseal Emphysematous Lung Sealant System
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	06-08-2012
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)
Approved WMO Date:	20-04-2013
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	NCT01449292
CCMO	NL40785.042.12