# 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

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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

**Public** AERIS Therapeutics

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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

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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
Туре:	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

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# **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** ClinicalTrials.gov CCMO ID NCT01449292 NL40785.042.12