A Prospective, Randomized, Placebo-Controlled Multicenter Study to Evaluate the Performance of the IBV Valve System for the Treatment of Severe Emphysema

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The objective of this randomized, blinded, multicenter, controlled study is to compare the performance of the IBV* Valve System (treatment group) to a control group receiving a sham bronchoscopy procedure without valve placement

Ethical review	Not approved
Status	Will not start
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON30950

Source
ToetsingOnline

Brief title
The Spiration IBV Valve system study

Condition

- Bronchial disorders (excl neoplasms)

Synonym
severe emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Spiration Inc.

Source(s) of monetary or material Support: Sponsor

Intervention

Keyword: dyspnea, emphysema, valve system

Outcome measures

Primary outcome

The study outcome will be the difference between the response rates of the

treatment and control groups in disease-related health status as measured by

the St. George*s Respiratory Questionnaire (SGRQ) total score and lung volume

change as measured by CT scan at 3 months.

Secondary outcome

No secundary study parameters.

Study description

Background summary

The Spiration IBV* Valve System is a device implanted in the lung airway intended to treat diseased or damaged lung. The valve limits airflow to selected areas, which improves health status.

Study objective

The objective of this randomized, blinded, multicenter, controlled study is to compare the performance of the IBV* Valve System (treatment group) to a control group receiving a sham bronchoscopy procedure without valve placement

Study design

This is a multicenter, prospective, randomized, blinded, placebo controlled study designed to evaluate treatment with the Spiration® IBV* Valve System compared to treatment with no valves implanted in the control group. The control group will be treated and tested in the same fashion as the treatment group, except that there will be no valves placed during the bronchoscopic procedure.

Subjects in the control group who have completed the 3-month testing and all follow-up visits will be evaluated for any co-morbidities or contraindications for treatment with IBV* Valve System. If none, the rollover subjects will receive treatment with the IBV* Valve System and then be evaluated after 3 months.
In this study, 100 subjects will be enrolled at up to 15 study sites. Subjects will be randomized in a 1:1 allocation ratio to either the IBV* Valve treatment group or the control group.

Intervention

All study subjects will be evaluated and tested at the same intervals, i.e., baseline, 1 month, 3 months, and 6 months. During the bronchoscopic procedure, to be performed on study Day 0, study subjects will be randomized to either the treatment or control group using a computer-generated randomization schema.

Subjects assigned to the treatment group will receive IBV* Valve treatment. Subjects in the control group will receive the same procedure, anesthesia, and a diagnostic bronchoscopy, but no valves will be placed. All subjects will be monitored through the 3-month follow-up visit.

Subjects in the control group who have completed the 3-month testing and follow-up visits will be evaluated for continued eligibility according to the protocol inclusion/exclusion criteria. If still eligible, they will receive treatment with the IBV* Valve System and be followed in accordance with the Summary of Crossover Tests and Procedures in Appendix B.

Study burden and risks

Risk analysis was performed to assess potential hazards that might be associated with the IBVTM Valve System. Failure Mode and Effects Analyses (FMEA) were conducted on both the design and manufacture of the system components including the valve, deployment catheter, and airway sizing kit. The FMEAs cover the patient, operator, clinical environment, and the products during shipping, intended use, and storage. The Spiration, Inc. FMEAs are controlled documents reviewed and approved by designated functions to ensure that appropriate considerations are made.

The results of the risk analyses show that the risk levels are acceptable when weighed against the benefits from the IBVTM Valve System. Spiration management considers the risks and benefits of accepting any conditions with risk levels above the established threshold, and as they occur, management ensures action plans to reduce the risks are effectively implemented.

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

Subject is between 40 and 74 years of age.
Subject has predominantly upper lobe, emphysema and severe dyspnea.

Exclusion criteria

Subjects with FEV1 and DLCO < 20% of predicted.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	10
Type:	Anticipated

Medical products/devices used

Generic name:	IBV Valve system
Registration:	Yes - CE intended use

Ethics review

Not approved

Date:	07-09-2007
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL18123.098.07