

U.S. Pivotal Trial of IBV[®] Valve System for Severe Emphysema

The IBV Valve Trial is a U.S. pivotal trial to evaluate safety and effectiveness of the IBV Valve System for the treatment of severe emphysema.

The IBV Valve Trial Design

The IBV Valve Trial is a prospective, randomized, blinded clinical trial that will enroll up to 500 patients at up to 40 sites in the United States. The objective of the study is to demonstrate the safety and effectiveness of the IBV Valve treatment. The primary endpoints of the study will be measured at six months. Patients enrolled in the control arm of the study will be eligible to receive treatment with the IBV Valve System after completion of the six-month study period.

A Blind Controlled Trial

The control for the study will be a “sham” treatment group: this group will be tested, treated and followed in an identical manner as the treatment group, except that no valves will be placed during the diagnostic bronchoscopy in the sham procedure.

Each clinical site will have two teams. One of the teams will be blinded to the study group assignment to preserve the integrity of the study plan. The investigator and assistants performing the procedure and randomization will not be blinded. After hospital discharge, the patient will be under the care of the blinded investigator and team, who will perform all follow-up evaluations.

Safety and Effectiveness Endpoints

The primary safety endpoint will be the difference between the treatment and control groups in the incidence of a composite of serious adverse events during the six-month study period.

The primary effectiveness endpoint of the study will be the difference between responder rates of the treatment and control groups at six months. Responders are defined as subjects with clinically meaningful improvements in disease-related health status as measured by the St. George’s Respiratory Questionnaire (SGRQ) total score and regional lung volume changes as measured by quantitative CT scan at six months.

Inclusion Criteria

The study is open to men and women age 40 to 74 who have been diagnosed with predominantly upper lobe emphysema and shortness of breath with exertion. Eligible patients are able to participate in pulmonary function and standardized exercise tests, have not smoked for four months and are willing to not smoke during the trial, and will commit to visits to a medical center for initial health assessment tests. Additional criteria must be met for participation in the study. For more information visit www.emphysematrial.com or call (877) 547-8839.

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