The LIBERATE Study

A multicenter, multinational randomized controlled trial of Zephyr® Endobronchial Valves in patients with heterogenous emphysema and little or no collateral ventilation

“The benefits are comparable to those seen with LVRS but with a reduction in post-procedure morbidity.”


METHODS & ENDPOINTS

- First multicenter RCT to evaluate effectiveness and safety of Zephyr® Endobronchial Valves in patients with little or no collateral ventilation (CV) out to 12 months.
- 190 subjects with hyperinflation (RV, 225% pred.; FEV₁, 27% pred.; DLCO, 34% pred.) randomized 2:1 (128 Zephyr EBV: 62 SoC).

STUDY DESIGN

909 Subjects consented

- 2 Withdrew consent
- 4 Died
- 1 Excluded for medical reasons

190 Subjects randomized

Zephyr EBV (N=128)

SoC (N=62)

121 Active subjects at 45 days

45-day follow-up

62 Active subjects at 45 days

- 1 Died
- 2 Excluded for medical reasons

120 Active subjects at 6 months

6-month follow-up

59 Active subjects at 6 months

- 1 Unwiling to return for follow-up visits

119 Active subjects at 12 months

12-month follow-up

59 Active subjects at 12 months

- 2 Missed 12-month visit
- 2 Not evaluated because of ongoing AEs – both subsequently died in Year 2

117 In long-term follow-up

43 Active crossover subjects

- 8 Pending crossover procedures
- 7 Excluded for medical reasons
- 1 Died

719 Subjects excluded

- 13 Withdrew consent
- 706 Screen failures
- 65 No eligible CV-lobe
- 280 Heterogeneity/destruction score
- 156 PFTs/lung volumes
- 145 Medical history, age, BMI, smoking history
- 49 Blood chemistry
- 11 Other

RESULTS IN ITT POPULATION

CONCLUSION

Zephyr® Endobronchial Valve treatment in carefully selected patients with little or no collateral ventilation in the target lobe provides clinically meaningful and statistically significant benefits in lung function, exercise tolerance, dyspnea and quality of life over current standard of care medical therapy out to at least 12 months.