THE STELVIO STUDY

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The first prospective randomized controlled trial using Chartis® to select candidates for Endobronchial Valve (EBV) treatment

"Endobronchial-valve treatment in patients with emphysema and a proven absence of interlobar collateral ventilation provided a measurable clinical benefit, with significantly improved lung function, exercise capacity, and quality of life as compared with usual care."*

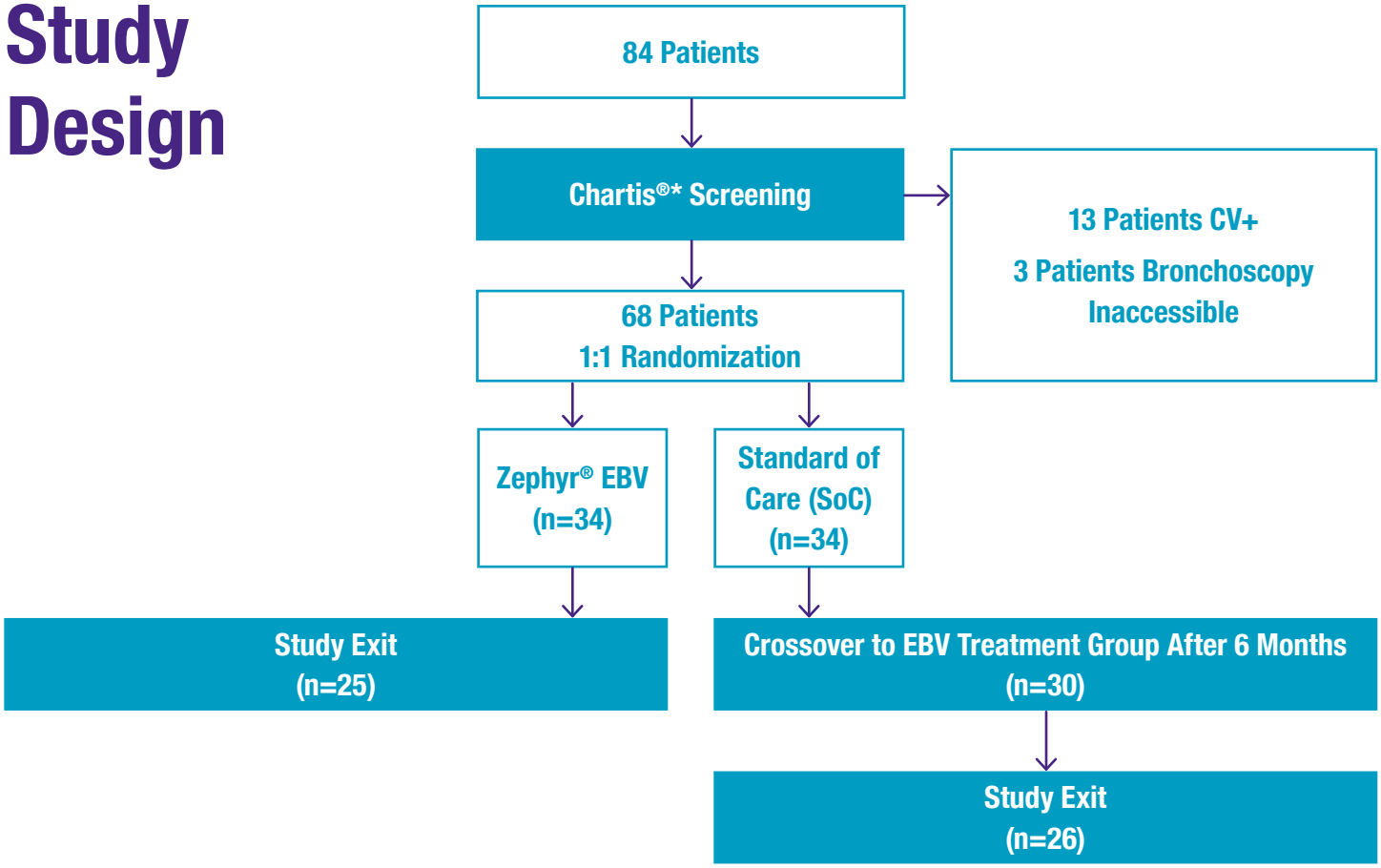
Methods & Endpoints

- 68 patients were confirmed with the Chartis System to be collateral ventilation (CV) negative and likely responders to Zephyr® EBV therapy, and randomized 1:1 to either EBV therapy or medical management.
- Primary outcome measures were differences between groups for changes in FEV_1, FVC, and 6-minute walk distance (6MWD) from baseline to 6 months.

*SOURCE: Klooster, K, ten Hacken, NH, Hartman, JE, Kerstjens, HA, van Rikxoort, EM and Slebos, DJ. Endobronchial valves for emphysema without interlobar collateral ventilation. New England Journal of Medicine, 2015;373(24), 2325-2335.

zephyr® valve

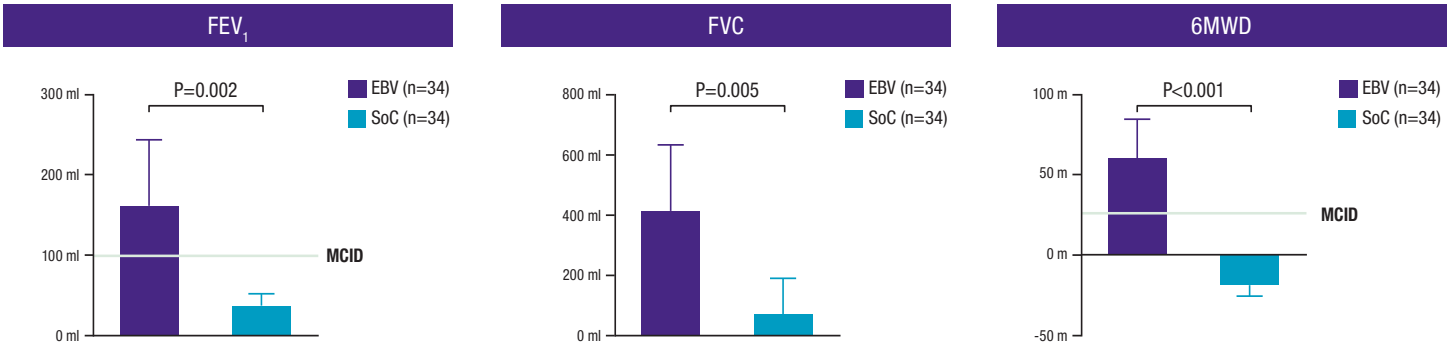
Study Design



Results

Primary Outcomes in the Intention-to-Treat Population

Mean change from baseline to 6 months.



	EBV Treatment Group	SoC	Δ
FEV_1	+20.9%	+3.1%	+17.8%
FVC	+18.3%	+4.0%	+14.4%
6MWD	+19.6%	-3.6%	+23.3%

SOURCE: Klooster, K, ten Hacken, NH, Hartman, JE, Kerstjens, HA, van Rikxoort, EM and Slebos, DJ. Endobronchial valves for emphysema without interlobar collateral ventilation. New England Journal of Medicine, 2015;373(24), 2325-2335. + Supplementary Appendix

*The STELVIO trial was performed as an independent physician initiated and conducted trial. Pulmonx was not involved in any part of the study.

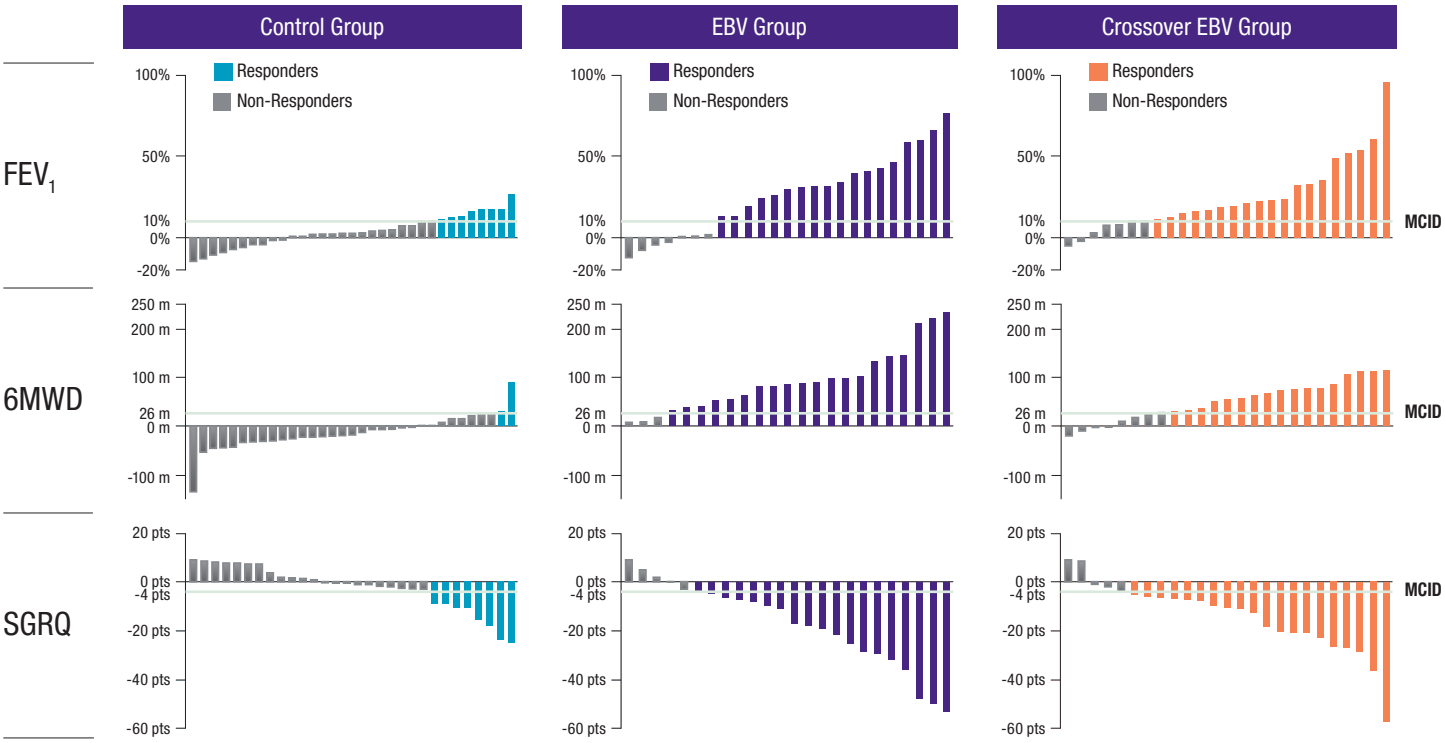
Clinical Benefits for Both Homogeneous and Heterogeneous Emphysema Subgroups*

Effectiveness outcomes for all EBV-treated patients who completed the study. Mean change from baseline.

	Homogeneous emphysema (n=29)	Heterogeneous emphysema (n=22)
FEV_1 (%)	+20.1	+32.6
RV (%)	-16.3	-16.6
6MWD (meters)	+69	+72
SGRQ (points)	-13	-19

Significantly Greater Responder Rates for EBV-treated Patients than Standard of Care

MCID responder results among patients who completed the study.



Conclusion

Endobronchial valve treatment significantly improved pulmonary function and exercise capacity in patients with severe emphysema characterized by an absence of interlobar collateral ventilation.

*Klooster, K, ten Hacken, NH, Hartman, JE, Kerstjens, HA, van Rikxoort, EM and Slebos, DJ. Endobronchial valves for emphysema without interlobar collateral ventilation. New England Journal of Medicine, 2015;373(24), 2325-2335. + Supplementary Appendix

United States

Brief Statement: The Pulmonx Zephyr® Endobronchial Valves are implantable bronchial valves indicated for the bronchoscopic treatment of adult patients with hyperinflation associated with severe emphysema in regions of the lung that have little to no collateral ventilation. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; Patients with evidence of active pulmonary infection; Patients with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); Patients with known allergies to silicone; Patients who have not quit smoking; Patients with large bullae encompassing greater than 30% of either lung. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial Valve System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

Brief Statement: The Chartis® System is indicated for use by bronchoscopists during a bronchoscopy in adult patients with emphysema, a form of Chronic Obstructive Pulmonary Disease (COPD), in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information. The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances. Use is restricted to a trained physician. Prior to use, please reference the Chartis System Instructions for Use/ User Manual for more information on indications, contraindications, warnings, all precautions, and adverse events.

Caution: Federal law restricts this device to sale by or on the order of a physician.

International

Brief Statement: The Zephyr® Endobronchial Valve is an implantable bronchial valve intended to control airflow in order to improve lung functions in patients with hyperinflation associated with severe emphysema and/or to reduce air leaks. The Zephyr Valve is contraindicated for: Patients for whom bronchoscopic procedures are contraindicated; Evidence of active pulmonary infection; Patients with known allergies to Nitinol (nickel-titanium) or its constituent metals (nickel or titanium); Patients with known allergies to silicone; Patients who have not quit smoking. Use is restricted to a trained physician. Prior to use, please reference the Zephyr Endobronchial System Instructions for more information on indications, contraindications, warnings, all precautions, and adverse events.

Brief Statement: The Chartis® System is indicated for use by bronchoscopists during a diagnostic bronchoscopy in adult patients with Chronic Obstructive Pulmonary Disease (COPD) and emphysema in a bronchoscopy suite. The system, composed of the Chartis Catheter and Chartis Console, is designed to measure pressure and flow in order to calculate resistance to airflow and quantify collateral ventilation in isolated lung compartments. The Chartis Catheter is used through the working channel of a bronchoscope and connects to the Chartis Console. The Chartis Console is capital equipment that is reusable and displays the patient information. The Chartis System is contraindicated in the presence of active infection or major bleeding diathesis. There are no known interfering substances. Use is restricted to a trained physician. Prior to use, please reference the Chartis System Instructions for Use/User Manual for more information on indications, contraindications, warnings, all precautions, and adverse events.

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