The IMPACT Trial

The first prospective randomized controlled trial of Zephyr® Endobronchial Valves (EBV) specifically in patients with homogeneous emphysema and no collateral ventilation.

"EBV therapy in selected patients with homogeneous emphysema without collateral ventilation results in clinically meaningful benefits of improved lung function, exercise tolerance and quality of life. Given the very limited treatment options available for this patient population, EBV therapy should be considered in these patients."

METHODS

- 93 patients with homogeneous emphysema were confirmed with the Chartis System to be CV negative and likely responders to Zephyr EBV treatment and randomized 1:1 to either EBV treatment or medical management.
- For EBV-treated patients, target lobes were selected based on emphysema destruction scores and regional perfusion impairments and were then completely occluded with valves.
- If patients did not feel a benefit, the valve position was assessed at 30 days by CT and repositioned if necessary.

STUDY DESIGN

Consented Subjects Assessed for Eligibility (n=183)

EBV Group (n=43)  Standard of Care (SoC) Group (n=50)

EBV Group at 3 Months (n=33)  SoC Group at 3 Months (n=46)

EBV Group at 6 Months and 1 Year  SoC Group at 6 Months

Study Exit  Crossover to EBV Group  Study Exit

90 Excluded
87 Screen failures
- Heterogeneity (n=23)
- PFTs/lung volumes (n=11)
- Perfusion (n=20)
- Nodules (n=5)
- Other reasons (n=11)
- Positive collateral ventilation (n=17)

• Follow-up outside window (n=6)
• Withdrawn (n=4)

RESULTS

Primary Outcome in the Intention-to-Treat Population
Percent change from baseline to 3 months

Secondary Outcomes in the Intention-to-Treat Population
Change from baseline to 3 months

CONCLUSION
Patients with homogeneous emphysema can achieve clinically meaningful benefits in lung function, exercise tolerance and quality of life with endobronchial valve treatment when they are pre-selected for absence of collateral ventilation and have complete lobar occlusion.