New Clinical Trial for Severe Emphysema/COPD Patients

Seeking Volunteers Across Australia

The CONVERT II Trial is a clinical study designed to evaluate the safety and efficacy of a new minimally invasive treatment to help people suffering with severe emphysema/COPD. Participants will receive study-related care at no cost.

Who Can Participate?

You may be eligible if:

- You are between 40 and 80 years old
- You have been diagnosed with severe emphysema/COPD
- You have stopped smoking for at least 8 weeks before enrolling

Who Cannot Participate?

You may not be eligible if:

- You have had prior lung surgery or a lung transplant
- You have been hospitalized three or more times in the past year due to emphysema/COPD
- Your primary diagnosis is asthma or chronic bronchitis
- You require invasive ventilatory support

If you're unsure about your eligibility, speak to your doctor or specialist.

For more information on the CONVERT II Trial scan QR code or visit *pulmonx.com.au/CONVERTII*

Interested in participating? Talk to your doctor or specialist to see if you qualify and arrange a referral to a trial site.

CONVERT II by pulmonx

About the **CONVERT II Study**

The CONVERT II Trial (NCT06035120) is an international study evaluating the AeriSeal® System's ability to limit collateral ventilation (CV) in patients with severe COPD/emphysema.

Collateral ventilation occurs due to naturally occurring openings in the lung fissures, preventing some patients from benefiting from bronchoscopic lung volume reduction (BLVR) with endobronchial valves (EBVs), a minimally invasive treatment.

The AeriSeal System is designed to seal these openings in the targeted lobe, effectively blocking collateral ventilation. Successful treatment with the AeriSeal System is followed by placement of endobronchial valves, a guideline-based treatment for patients with severe emphysema/COPD.

Endobronchial valves (EBVs) are small, one-way valves used to reduce lung hyperinflation, the primary cause of breathlessness in patients with severe COPD/emphysema. If collateral ventilation is present, the treated lobe will not deflate, and the valves are not effective.
EBVs have been clinically proven to improve breathing, lung function, and quality of life for patients with advanced disease.[1]

For more details,visit: *pulmonx.com.au/CONVERTII*

Speak with your doctor or specialist to see if you qualify and request a referral to a participating trial site.

Participating Trial Sites & Contact Information

New South Wales

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Queensland

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South Australia

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All medical and surgical procedures can have side effects. Refer to the Informed Consent for a detailed list of potential side effects. Participants may have none, some, or all of the effects listed, and they may be mild, moderate, or severe. If you have any of these side effects, or are worried about them, talk with the study doctor. The study doctor will also be looking out for side effects.

The CONVERT II Study has been granted ethics approval from Macquarie University Clinic Human Research Ethics Committee (HREC), Wesley Research Institute Human Research Ethics Committee, and Royal Adelaide Hospital Human Research Ethics Committee.

The study will be conducted in accordance with the Declaration of Helsinki, the guidance of the International Council on Harmonization (ICH) Guidelines for Good Clinical Practice (E6 R2), the MDR Regulations (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, Title 21 of the FDA Code of Federal Regulations, Good Clinical Practice (Parts 812, 11, 50, 54, 56), Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155:2020), and other applicable local and federal regulations, including the archiving of essential documents.

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