



## SHIELD Study

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Trial title	The SHIELD Whole Lung Lavage Observational Cohort Study
Trial synopsis	This study is for people who have silicosis and are scheduled to undergo a whole lung lavage (WLL) as part of their care. Silicosis is a scarring condition of the lungs caused by inhaling silica dust and is difficult to treat. The research project is aiming to understand the effectiveness of whole lung lavage (WLL) as a treatment option for silicosis.
Investigational medicinal product, comparator and randomisation	Whole Lung Lavage, Observational Cohort Study
Disease target	Silicosis or silica induced bronchitis
Sponsor	University of Queensland
Duration	3 years
Trial Status	Recruiting
Trial phase	N/A
Key inclusion criteria	<p>Key inclusion criteria:</p> <ul style="list-style-type: none"><li>• Adults <math>\geq</math> 18 years who are scheduled for WLL as part of their routine clinical care</li><li>• History of exposure to respirable crystalline silica (RCS) while working in at-risk industry</li><li>• Elimination of workplace exposure to RCS for a minimum of 6 months</li><li>• Ground glass nodularity &gt; extent of solid nodularity on HRCT as judged by investigator or evidence of silica-induced bronchitis</li><li>• Evidence of disease progression in the past two years, defined as any of<ul style="list-style-type: none"><li>○ A relative decline in FVC or FEV1 of at least 5% of the predicted value</li><li>○ Worsening of respiratory symptoms</li><li>○ Increased extent of silicosis on high resolution CT scan</li></ul></li></ul>



Key exclusion criteria	Key exclusion criteria: <ul style="list-style-type: none"><li>• Ongoing workplace exposure to RCS or removal of workplace exposure of less than 6 months</li><li>• Progressive massive fibrosis (PMF) defined as areas of confluent fibrosis with diameter &gt;10mm on HRCT</li><li>• FEV1 or FVC &lt;50% predicted</li><li>• DLCO &lt;50% predicted</li><li>• Contraindication to WLL as judged by the investigator</li><li>• Actively or imminently listed for lung transplantations</li><li>• Females with positive pregnancy test at screening or currently breastfeeding</li><li>• Significantly impaired cardiac function</li><li>• Any history of malignancy likely to result in significant disability or likely to require significant medical or surgical intervention within the next 24 months</li><li>• Any history of malignancy likely to result in significant disability or likely to require significant medical or surgical intervention within the next 24 months</li></ul>
Number of participants sought	30
Lead site(s) in Australia	The Prince Charles Hospital (QLD)
Lead site(s) in New Zealand	N/A
Additional sites	<ul style="list-style-type: none"><li>• The Alfred Hospital (VIC)</li><li>• Royal Prince Alfred Hospital (NSW)</li></ul>
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