Centre of Research Excellence in Pulmonary Fibrosis
PACT PF Australasian Clinical Trials

SHIELD Study

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	Key inclusion criteria: • Adults >= 18 years who are scheduled for WLL as part of their routine clinical care • History of exposure to respirable crystalline silica (RCS) while working in at at-risk industry • Elimination of workplace exposure to RCS for a minimum of 6 months • Ground glass nodularity>extent of solid nodularity on HRCT as judged by investigator or evidence of silica-induced bronchitis • Evidence of disease progression in the past two years, defined as any of o A relative delice in FVC or FEV1 of at least 5% of the predicted value o Worsening of respiratory symptoms o Increased extent of silicosis on high resolution CT scan

Key exclusion criteria	Key exclusion criteria: • Ongoing workplace exposure to RCS or removal of workplace exposure of less than 6 months • Progressive massive fibrosis (PMF) defined as areas of confluent fibrosis with diameter >10mm on HRCT • FEV1 or FVC<50% predicted • DLCO <50% predicted • Contraindication to WLL as judged by the investigator • Actively or imminently listed for lung transplantations • Females with positive pregnancy test at screening or currently breastfeeding • Significantly impaired cardiac function • Any history of malignancy likely to result in significant disability or likely to require significant medical or surgical intervention within the next 24 months • Any history of malignancy likely to result in significant disability or likely to require significant medical or surgical intervention within the next 24 months
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	• The Alfred Hospital (VIC) • Royal Prince Alfred Hospital (NSW)
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