Centre of Research Excellence in Pulmonary Fibrosis

Lung Foundation Australia
Pulmonary Fibrosis Clinical Trials

PACT – Clinician
New Clinical Trial and Research

Trial title	The SHIELD Whole Lung Lavage Observational Cohort Study
Trial synopsis	A national, multi-site, observational cohort study that will investigate the efficacy of whole lung lavage (WLL) as a treatment option for people with silicosis or silica induced bronchitis due to a history of exposure to respirable crystalline silica (RCS).
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	

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
	  ○ A relative delice in FVC or FEV_1 of at least 5% of the predicted value
	  ○ Worsening of respiratory symptoms
	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 • FEV_1 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
Primary endpoint	Change in dual blind read CT ICOERD score from baseline to 3 months post WLL
Number of participants sought	n=30
Lead site(s) in Australia	The Prince Charles Hospital
Lead site(s) in New Zealand	Not applicable
Additional sites	The Alfred Hospital, Melbourne Royal Prince Alfred, Sydney
Contact	pactcoordinator@cre-pf.org.au