Clinician - PACT
New Clinical Trial and Research

Trial title	The COLDICE Trial: Cryobiopsy versus Open Lung biopsy in the Diagnosis of Interstitial lung disease allianCE
Trial synopsis	The transbronchial lung cryobiopsy (TBLC) is a new, minimally invasive technique for obtaining lung tissue to diagnose interstitial lung disease (ILD). In order to determine the place of cryobiopsy in ILD diagnostic algorithms and international guidelines, it is crucial that this procedure is validated against the current gold-standard practice, the video assisted thoracoscopic surgical (VATS)lung biopsy. This study brings together a team of leading proceduralists, ILD specialists and histopathologists from across Australia, with consultative input from international leaders in the field. The main objective of this project is to determine the role of cryobiopsy in the diagnosis of ILD. All enrolled subjects will undergo both types of biopsy (TBLC and VATS biopsy) within the one procedure, under general anaesthesia. Following the procedure and local analysis, specimens will be sent to the reference centre for further evaluation
Investigational medicinal product, comparator and randomisation	Video assisted thoracoscopic surgical lung biopsy - the current gold-standard for obtaining lung tissue for diagnosis of parenchymal lung disease compared to Transbronchial lung cryobiopsy - a recently developed technique involving the bronchoscopic insertion of a frozen-tipped probe into peripheral airways for extraction of lung tissue specimens for diagnostic purposes.
Disease target	Interstitial Lung Disease
Sponsor	Sydney Local Health District - RPAH
Duration	A short-term intervention with follow up phone calls at 6 weeks, 6 months and study conclusion
Trial Status	Study completed
Trial phase	4

Key inclusion criteria	- Patients assessed as requiring histopathology for the diagnosis of their ILD (at specialist multidisciplinary team meetings), and considered suitable for VATS lung biopsy - 18 - 80 Years - Both males and females
Key exclusion criteria	- Age > 80 - Resting oxyhaemoglobin saturation under 90% - Systolic pulmonary artery pressure over 40mmHg on echocardiogram - BMI > 40 - Platelets less than 100 - INR > 1.5 - Advanced comorbidities (including poorly controlled systemic hypertension, congestive cardiac failure, unstable angina, significant stroke). - History of adverse reaction to general anaesthesia - Inability to provide informed consent
Primary endpoints	1) Diagnostic yield as measured by the proportion of cryobiopsy specimens where confident histopathological diagnosis can be made compared with VATS biopsy findings, as assessed by expert pathologists. 2) Agreement between the consensus diagnosis following the presentation of clinical-radiological-cryobiopsy and clinical-radiological-VATS data at multi-disciplinary team discussion
Number of participants sought	66
Lead site(s) in Australia	Royal Prince Alfred Hospital
Lead site(s) in New Zealand	N/A
Additional sites	1) Royal Prince Alfred Hospital, Camperdown NSW, 2) Liverpool Hospital, Liverpool NSW, 3) Macquarie University Hospital, Macquarie Park NSW, 4) Nepean Hospital, Kingswood NSW, 5) Royal North Shore Hospital, St Leonards NSW, 6) John Hunter Hospital Royal Newcastle Centre, New Lambton NSW, 7) Westmead Hospital, Westmead NSW,

	8) Sir Charles Gairdner Hospital, Nedlands WA, 9) Fiona Stanley Hospital, Murdoch WA
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