Clinician - PACT
New Clinical Trial and Research

Trial title	PFOX: Pulmonary Fibrosis Ambulatory Oxygen Trial
Trial synopsis	The fibrotic interstitial lung diseases (fILD) are characterised by lung scarring, distressing breathlessness and poor health-related quality of life. Exertional desaturation during exercise is a hallmark of fILD, occurring in over 50% of patients. It is sometimes treated with ambulatory oxygen therapy (AOT), however, the absence of clinical trials has given rise to marked variations in policy and practice globally. Even where AOT is available, treatment adherence using the traditional delivery method of cylinder gas is often poor. Recently portable oxygen concentrators (POCs), have become available, which are lighter and more manoeuvrable than a cylinder. This may enhance adherence and maximize treatment benefits. This trial will determine the clinical benefits and societal costs of AOT for people with fILD and exertional desaturation. A total of 260 participants with fILD and exertional desaturation will be randomly assigned to use either AOT or air (sham) delivered using identical POCs for 6 months. Participants, researchers and health professionals will be blinded to group allocation. The primary outcome is physical activity, measured as steps per day. Secondary outcomes include exercise capacity, health-related quality of life, dyspnoea, fatigue, anxiety and depression. An embedded economic analysis will be undertaken. The results of this trial will provide certainty regarding the impact of ambulatory oxygen therapy in people with fILD.
Investigational medicinal product, comparator and randomisation	[Investigational product: Inogen One G3 portable oxygen concentrator; Randomisation: 1:1 in 2 groups: 1: Ambulatory oxygen therapy using portable oxygen concentrator (Inogen One G3 HF) 2: Sham ambulatory oxygen therapy using identical portable oxygen concentrator
Disease target	Fibrotic interstitial lung disease
Sponsor	Monash University
Duration	6 months
Trial Status	Recruiting
Trial phase	Phase III

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Key inclusion criteria	-Age> 18 years -Diagnosis of fibrotic interstitial lung disease -Stable pharmacotherapy over the last 3 months -Presence of exertional desaturation (SpO2≤88% for at least 10 consecutive seconds during 6MWT -Able to read and speak English
Key exclusion criteria	-Currently using or eligible for long term oxygen therapy -Currently participating in pulmonary rehabilitation -Non-ambulant -Current smoker; Currently pregnant -Death or transplant anticipated within the duration of the trial (6months) -Cognitively unable to consent -Admitted to an acute care hospital within 30 days
Primary endpoint	Change in physical activity
Number of participants sought	260
Lead site(s) in Australia	Alfred Health (Vic)
Lead site(s) in New Zealand	N/A
Additional sites	Austin Health (Vic) Royal Prince Alfred Hospital (NSW) The Prince Charles Hospital (Qld) The Royal Melbourne Hospital (VIC)
Contact person	pactcoordinator@cre-pf.org.au