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

CORAL Trial

Trial title	CORAL: Cough Reduction in IPF with nalbuphine ER
Trial synopsis	Nalbuphine Extended-Release tablets (NAL ER) are being studied to treat cough in people who have idiopathic pulmonary fibrosis, which is also called IPF. IPF is a serious lung condition that affects breathing and approximately 85% of these patients experience a chronic cough. There is some research showing that other medicines similar to NAL ER may help reduce cough but there are currently no approved treatments. The purpose of this study is to understand oral NAL ER tablets safety and to find the best dose of NAL ER to treat cough in people with IPF. 3 out of every 4 participants will take varying doses of NAL ER and 1 out of every 4 participants will take placebo. A non-invasive cough monitor will be worn for 24 hours to objectively record the number of coughs and assess whether there is any change in the number of coughs while taking the study drug. During the 6 weeks of treatment, participants will return to the site for assessments approximately every 2 weeks.
Investigational medicinal product, comparator and randomisation	Nalbuphine Extended-Release tablets (NAL ER) Participants will be randomised (1:1:1:1) to either one of three NAL ER arms or placebo. BID dosing will consist of 2 tablets from matching placebo and the available strengths, to meet the desired dose.
Disease target	Chronic Cough in Idiopathic Pulmonary Fibrosis (IPF)
Sponsor	Trevi Therapeutics Inc.
Duration	Duration of Study for each participant: up to 12 Weeks Duration of Treatment for each participant: 6 Weeks
Trial Status	Recruiting
Trial phase	Phase IIb
Key inclusion criteria	• Diagnosis of IPF

	• Cough Severity Score ≥ 4 on CS-NRS (Cough Severity Numerical Rating Scale) • History of chronic cough for at least 8 weeks before screening. • SpO2 ≥ 92% (Saturation of Hemoglobin with Oxygen as Measured by Pulse Oximetry). • FVC ≥ 40% predicted of normal – Force Vital Capacity, as determined by spirometry. • DLCO ≥ 25% predicted of normal - Diffusing capacity of the lung for carbon monoxide within the last 12 weeks, or at the time of screening. • Males or females ages 18 years and older at the time of consent.
Key exclusion criteria	• Cannot currently be on continuous oxygen therapy for longer than 16 hours at any level or delivered by any modality. Intermittent oxygen use of any duration over any given 24-hour period is allowed. • Cannot have had upper or lower respiratory tract infection in the last 8 weeks prior to the baseline visit. • Cannot have clinical history of aspiration pneumonitis. • Cannot have diagnosis of sleep apnea. • Use of opiates including opiate-containing anti-cough agents, and naltrexone, benzodiazepines, and Monoamine oxidase inhibitors (MAOIs) are prohibited (washout permitted if clinically appropriate). • Oral corticosteroid cough treatment must be stopped 4 weeks prior to the baseline visit and for the duration of the study. • Medications prescribed as cough suppressants must be taken on a stable dose 14-days prior to the baseline visit and expected to remain on that dose for the duration of the study.

	• Anti-fibrotic medications must be on a stable dose for 8 weeks prior to the baseline visit and expected to remain on that dose for the duration of the study.
Number of participants sought	Approximately 160 participants with diagnosed IPF and experiencing chronic cough will be randomised.
Lead site(s) in Australia	• TrialsWest (WA) • Westmead Hospital (NSW)
Lead site(s) in New Zealand	N/A
Additional sites	• Eastern Health-Box Hill Hospital (VIC) • Austin Hospital (VIC) • Concord Repatriation General Hospital (NSW) • Respiratory Clinical Trials Pty Ltd. (SA)
Contact	enquiries@pactnetwork.com.au