Patient - PACT
New Clinical Trial and Research

Trial title	**The TELO-SCOPE Study: Attenuating Telomere Attrition with Danazol. Is there Scope to Dramatically Improve Health Outcomes for Adults and Children with Pulmonary Fibrosis.**
Trial synopsis	Pulmonary fibrosis is a scarring lung disease that in its most common and severe form (Idiopathic Pulmonary Fibrosis (IPF)) causes progressive respiratory failure and premature death. The genetic origins of Pulmonary Fibrosis have been recently described, with the most common abnormalities being in telomere related genes. Telomeres act as protective caps at the ends of chromosomes – somewhat like the hard plastic at the end of a shoelace that prevents the shoelace from fraying. Telomere shortening is a normal ageing process, however in some people with pulmonary fibrosis this shortening occurs more rapidly due to specific genetic abnormalities in the machinery that controls telomere length. Up to 25% of people with pulmonary fibrosis may have abnormally short telomeres. While it is possible to measure the length of the telomere, it is not currently routinely incorporated in clinical practice. Danazol is a synthetic hormone which may increase telomere length. A small study of danazol in a group of patients with blood disease related to telomere shortening demonstrated stabilisation of lung function. *The TELO-SCOPE study aims to evaluate the benefits and safety of danazol in addition to standard pulmonary fibrosis therapies (e.g. anti-fibrotics like pirfenidone and nintedanib) in patients with pulmonary fibrosis related to Short Telomeres*. TELO-SCOPE is a randomised controlled trial (RCT), which means that the medication, danazol, is tested against a placebo so that we can be confident that it either works or does not work. By randomly assigning participants to either the danazol or placebo groups, makes sure that other factors (like age or gender) don't influence the results in any way. RCTs provide the strongest data to be sure whether or not a treatment works. This is a phase II trial – which means that we are testing the effectiveness and safety of danazol in people who have pulmonary fibrosis. Danazol has already been tested in other conditions.
Investigational medicinal product	Danazol in addition to standard of care (e.g. pirfenidone or nintedanib). Background antifibrotic therapy is allowed as drug pharmacokinetics do not predict interactions or additive hepatotoxicity, but these will be a key focus of the safety assessments.
Disease target	Any fibrotic lung disease.
Sponsor	University of Queensland
Duration	12 months

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Trial Status	Recruiting
Lead site(s) in Australia	The Prince Charles Hospital QLD – John Mackintosh
Lead site(s) in New Zealand	Not applicable.
Additional sites	Active sites: • Royal Prince Alfred Hospital NSW – Tamera Corte • The Alfred VIC – Ian Glaspole Awaiting activation: • John Hunter Hospital NSW – Christopher Grainge • Sydney Children's Hospital NSW – Adam Jaffe • The Children's Hospital Westmead NSW – Hiran Selvadurai • Royal Adelaide Hospital SA – Paul Reynolds • The Austin VIC – Nicole Goh • Fiona Stanley Hospital WA – Jeremy Wrobel
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