Phase II Trial of Pirfenidone in Patients with Progressive Fibrosing Unclassifiable ILD (uILD)

Toby M. Maher,1 Tamarra J. Corte,2 Abyth Fischer,3 Michael Kreutzer,2 David J. Lederman,2 Maria Molina-Molina,3 Judi Asman,3 Klaus-Uwe Kerckhoffs,3 Katerina Samara,3 Frank Gilberg,3 Vincent Cotton4

1AHRF Respiratory Clinical Research Facility, Royal Brompton Hospital, London, UK; 2Fibrosis Research Group, National Heart and Lung Institute, Imperial College London, London, UK; 3Department of Respiratory Medicine, Royal Prince Alfred Hospital, Camperdown, New South Wales, Australia; 4AHRF Respiratory Clinical Research Facility, Royal Brompton Hospital, London, UK.

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We would like to thank the patients, their family members and participating staff at all of the study centres. We would also like to thank the independent Data Monitoring Committee (DMC) who reviewed the safety data collected during the study and advised on the analyses.

**REFERENCES**


**COMPLIANCE WITH ETHICAL STANDARDS**

This study was conducted in accordance with ethical standards as outlined in the Declaration of Helsinki and local laws.

**DATA AVAILABILITY**

The data sets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

**CONFLICTS OF INTEREST**

The authors declare no conflicts of interest.

**DATA SHARING STATEMENT**

The data that support the findings of this study are available on request from the corresponding author.

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**DISCLOSURES**

No potential conflicts of interest relevant to this article were reported.

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**ETHICAL APPROVAL**

No ethical approval was required for this observational study.

**REGISTRY**

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Pirfenidone; uILD; Interstitial lung disease; Efficacy; Safety; Asthma; COPD; IPF; ILD; DMC; Regulatory

**ADDRESS FOR CORRESPONDENCE**

Toby Maher, MBBCh, FRCP, Professor of Respiratory Medicine, Imperial College London, Department of Respiratory Medicine, Royal Brompton Hospital, Sydney Road, London, SW3 6NP, UK. Tel: +44 (0)20 7102 7983. Email: toby.maher@imperial.ac.uk

**ARTICLE INFO**

Phase II, 4-month, double-blind, placebo-controlled trial of 127 patients with unclassifiable interstitial lung disease (uILD). Primary endpoint was change in forced vital capacity (FVC) at week 24. Secondary endpoints included change in 6-minute walk distance, St. George’s Respiratory Questionnaire (SGRQ), and lung cancer screening using whole-body multidetector CT. Analysis showed a significant treatment effect (p = 0.001) compared to placebo on change in FVC after 24 weeks. At week 24, 79.6% of patients in the pirfenidone group had an absolute predicted change in FVC of > 20 mL compared to 56.4% in the placebo group (p = 0.015). On subgroup analysis, pirfenidone was more effective in patients with body weight > 60 kg (p = 0.020). No safety concerns were identified. Pirfenidone was well tolerated, and no serious adverse events attributable to treatment were reported.