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Pirfenidone reduces rate of lung decline in idiopathic pulmonary fibrosis

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The CAPACITY study, published Online First and in an upcoming *Lancet*, shows that pirfenidone reduces the rate of decline of lung function in patients with idiopathic pulmonary fibrosis—a condition of unknown cause affecting hundreds of thousands of patients worldwide that leads to progressive lung decline and kills four in five patients within five years. The Article is by Professor Paul W Noble, Duke University Medical Center, Durham, NC, USA, and colleagues.

In two concurrent trials, patients (aged 40-45 years) with idiopathic pulmonary fibrosis were randomly assigned to oral pirfenidone or placebo for a minimum of 72 weeks in 110 centres in Australia, Europe, and North America. The primary endpoint assessed in the studies was change in percentage predicted forced vital capacity (FVC) at week 72.

One study showed an 8.4% decline in mean FVC in the pirfenidone group compared to a decline of 12.4% in the placebo group, while 35 (20%) of 174 patients in the pirfenidone group, versus 60 (35%) of 174 patients in the placebo group, had a decline of at least 10%. IN the second study, the difference between groups in FVC change at week 72 was not significant (9.0% pirfenidone vs 9.6% placebo)

Patients in the pirfenidone group had higher incidences of nausea, indigestion, vomiting, anorexia and other adverse effects than did the placebo group. Fewer overall deaths (19 [6%] vs 29 [8%]) and fewer deaths related to idiopathic pulmonary fibrosis (12 [3%] vs 25 [7%]) occurred in the pirfenidone groups than in the placebo groups.

The authors say: "Idiopathic pulmonary fibrosis remains a progressive and fatal disorder, and no treatment so far has been shown to be efficacious, despite several clinical trials in the past decade. The orphan status of idiopathic pulmonary fibrosis, heterogeneity in rates of disease progression, and lack of a precedent for regulatory approval complicate efforts to develop novel treatments."

They conclude: "The data from these two multinational, double-blind, placebo-controlled phase 3 studies show the clinically meaningful benefit and favourable safety profile of pirfenidone in patients with idiopathic pulmonary fibrosis. In conclusion, pirfenidone has a favourable benefit-risk profile and represents a suitable treatment option for patients with idiopathic pulmonary fibrosis."

In a linked Comment, Dr Demosthenes Bouros, Medical School, Democritus University of Thrace, Alexandroupolis, Greece, points out that no drug is currently approved for use in idiopathic pulmonary fibrosis in the USA. He adds that the European Commission recently granted marketing authorisation for pirfenidone, after a positive recommendation from the Committee for Medicinal Products for Human Use for the treatment of adults with mild to moderate idiopathic pulmonary fibrosis, raising hopes for the estimated 100,000 people across Europe who have the condition.

More information: www.thelancet.com/journals/lan … (11)60405-4/abstract

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