

# INPLASY

## The efficacy of Pirfenidone combined with Acetylcysteine in the treatment of idiopathic pulmonary fibrosis

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### ADMINISTRATIVE INFORMATION

**Support** - Xian Medical College.

**Review Stage at time of this submission** - Data analysis.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY202520069

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 February 2025 and was last updated on 13 February 2025.

### INTRODUCTION

**Review question / Objective** The purpose of this study was to investigate the difference between the efficacy of pirfenidone combined with acetylcysteine in the treatment of idiopathic pulmonary fibrosis and that of pirfenidone alone in the treatment of idiopathic pulmonary fibrosis. If the combination treatment is more effective, further subgroup analysis will be conducted according to the dosage age of acetylcysteine.

**Condition being studied** Idiopathic pulmonary fibrosis is an unexplained, chronic, progressive lung disease characterized by irreversible fibrosis and scarring of lung tissue, which can lead to decreased lung function. IPF typically manifests as fibrosis and increased scar tissue in lung tissue, resulting in structural destruction of the alveoli and lung interstitium. Patients with IPF usually have progressive dyspnea on exertion, dry cough, fatigue, weakness, weight loss, and pulmonary function tests showing restrictive dyspnea and

decreased oxygenation. IPF affects about 3 million people worldwide and is largely unaffected by currently available drugs, with increasing morbidity and case fatality rates. The prognosis for IPF is generally poor, with a median survival of 3 to 5 years on average. The treatment of IPF is challenging, and lung transplantation may be the last resort for antifibrotic drug therapy. The goal of treatment is to slow disease progression, relieve symptoms such as dyspnea, and improve quality of life. Therefore, early diagnosis and pharmacological intervention for patients with IPF will be particularly important. In previous meta-analyses, pirfenidone combined with oral or inhaled acetylcysteine was not used as a separate group discussion for the therapeutic effect, and although guidelines recommend the inclusion of acetylcysteine in the adjuvant treatment of idiopathic pulmonary fibrosis, it is not clear which effect of pirfenidone plus inhaled or oral acetylcysteine is better. Therefore, in this meta-analysis, we will conduct a meta-analysis of relevant clinical studies to further explore the efficacy of pirfenidone in combination with oral or

inhaled acetylcysteine in the treatment of idiopathic pulmonary fibrosis and the efficacy, safety and tolerability of the combination drug and pirfenidone alone in the treatment of idiopathic pulmonary fibrosis.

## METHODS

**Participant or population** Patients with idiopathic pulmonary fibrosis.

**Intervention** Pirfenidone combined with acetylcysteine.

**Comparator** Treatment with pirfenidone alone.

**Study designs to be included** RCT.

**Eligibility criteria** Subjects were patients with IPF whose diagnosis was defined according to the American Thoracic Society (ATS) European Respiratory Society (ERS) Japanese Respiratory Society (JRS) Latin American Thoracic Society (ALAT) guidelines updated in 2022 :(1) Interstitial lung disease excluding other known etiology, such as residential and occupational environmental exposures, connective tissue diseases, and medications, as well as present Findings 2 or 3 below (2)UIP high-resolution CT findings (3) Patients with lung histology conform to a specific combination of high-resolution CT phenotype and lung pathological phenotype.

**Information sources** PubMed、EMBASE、Cochrane Library、Web of Science、China National Knowledge network、Wanfang、medical Wipu medical database.

**Main outcome(s)** FVC、FVC%、FEV1、DLCo%、6MWD、III-C、HA、UCSD-SOBQ score、CAT score, mortality rate, acute exacerbation rate, treatment effectiveness, etc.

**Quality assessment / Risk of bias analysis** Cochrane tool.

**Strategy of data synthesis** The STATA software was selected for data analysis, and the fixed-effect model was used to analyze the data. If 50% of I2 indicates large heterogeneity, random effects model is used for analysis.

**Subgroup analysis** Subgroup analysis was performed according to the dosage of pirfenidone 1200mg >1200mg. Acetyl cysteine was divided into oral inhalation subgroups for analysis.

Subgroup analysis was performed according to the age of patients with idiopathic pulmonary fibrosis,>60 years old.

**Sensitivity analysis** Stata software performs a sensitivity analysis to reflect the sensitivity of an article by how the effect size changes after one of the articles is deletedStata.

**Country(ies) involved** China.

**Keywords** Idiopathic pulmonary fibrosis, pirfenidone, acetylcysteine, combination therapy.

## Contributions of each author

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