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JOURNAL CLUB
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ARTICLE

Trial of a Preferential Phosphodiesterase 4B Inhibitor for Idiopathic Pulmonary Fibrosis. N Engl J Med. 2022 May 15. doi: 10.1056/NEJMoa2201737. Epub ahead of print. PMID: 35569036

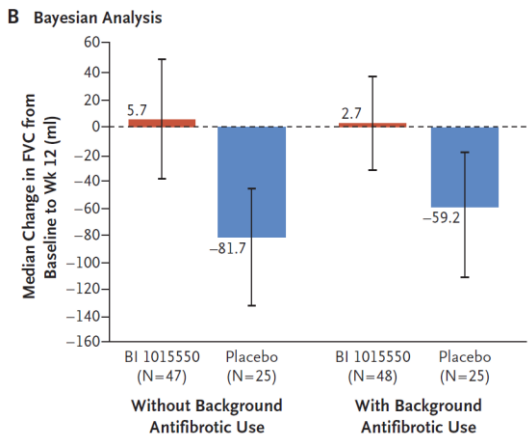
CLINICAL QUESTION

What is the efficacy and safety of BI 1015550, an oral preferential inhibitor of PDE4B subtype, in patients with IPF?

SUMMARY

Idiopathic pulmonary fibrosis is a progressive interstitial lung disease with high mortality. There are currently two FDA approved antifibrotic drugs available that slow, but not stop, progression of fibrotic lung disease. Phosphodiesterase 4 (PDE4) inhibition is associated with anti-inflammatory and antifibrotic properties. Thus, preferential inhibition of the PDE4B subtype may be beneficial in the treatment of IPF.

This study is a phase 2, double-blind, placebo-controlled trial conducted to investigate the safety and efficacy of BI 1015550, an oral inhibitor of the PDE4B subtype in patients with IPF. 147 patients were randomly assigned in a 2:1 ratio to receive BI 1015550 at a dose of 18mg twice daily or placebo. The primary end point was the change from baseline in the forced vital capacity (FVC) at 12 weeks. Data was analyzed with a Bayesian approach separately according to background use or nonuse of antifibrotic therapy.



For patients with IPF, treatment with BI 101550 prevented a decrease in lung function over 12 weeks. The sample size was small and the results need to be confirmed in a larger trial. The safety profile of BI 101550 warrants further research in a phase III trial.

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