

Do Both Albuterol and Budesonide Contribute to the Efficacy of a Combination Pressurized Metered-Dose Inhaler in Patients With Asthma?

STUDY DESIGN

Phase 3, double-blind, randomized MANDALA trial

989 patients with mild/moderate asthma >12 years

Randomized to:

4x daily albuterol-budesonide 180/160 µg

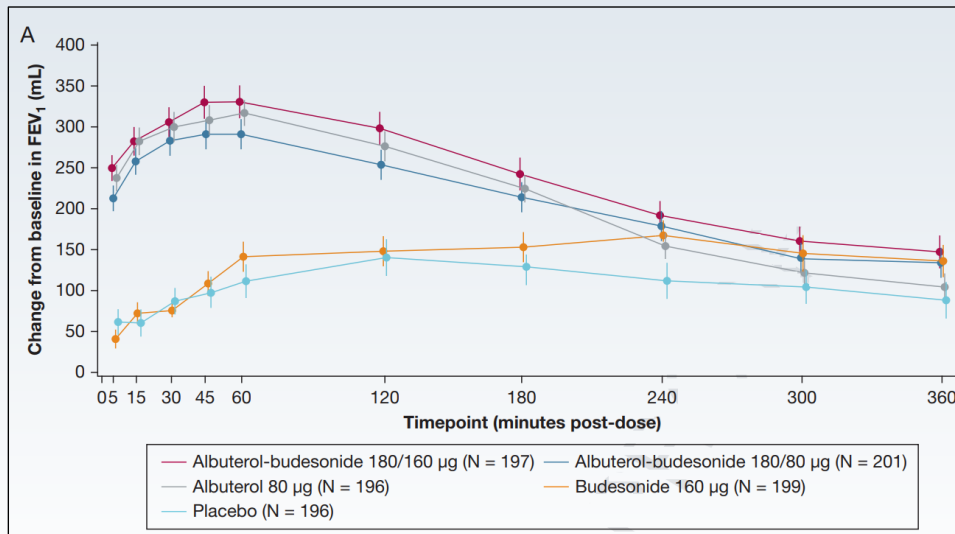
4x daily albuterol-budesonide 180/80 µg

Albuterol 180 µg

Budesonide 160 µg

Placebo

RESULTS



Change in baseline FEV₁ on day 1

Change in baseline FEV₁ over 12 weeks was greater with **combination** vs budesonide 160 µg



Change in trough FEV₁ at week 12 was greater with **combination** vs albuterol 180 µg

In patients with asthma, both albuterol and budesonide monocomponents contributed to the combination albuterol-budesonide inhaler's lung function efficacy and were well tolerated, supporting the inhaler's use as a novel rescue therapy.