#7419 - Effects of single inhaler combinations of extrafine BDP/FF/G and extrafine BDP/FF on lung hyperinflation and exercise endurance time in subjects with COPD: a randomised controlled trial

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BACKGROUND AND AIM

This study compared the effect of triple combination beclometasone dipropionate / formoterol fumarate / glycopyrronium **(BDP/FF/G)** 100/6/10 µg/actuation, double combination **BDP/FF** 100/6 µg/actuation and **placebo** administered as 2 inhalations twice daily for 3 weeks via pressurized metered dose inhalers on **lung hyperinflation and exercise endurance time (EET)** in subjects with **chronic obstructive pulmonary disease (COPD).**

STUDY DESIGN

This was a phase 4 randomized, double blind, 3-period cross-over, placebo-controlled study in patients with moderate-to-severe COPD and evidence of hyperinflation. The primary endpoint was **change from baseline in 2-hour post-dose inspiratory capacity at the end of each 3-week treatment.** Key-secondary endpoints included **change from baseline in IC at isotime** (shortest EET at either the start or end of each treatment period) and **2-hour post-dose EET.**

BASELINE CHARACTERISTICS

A total of **181 patients were screened, 106 were randomised and 95 (89.6%) completed the study.** Among the 11 who withdrew from the study, eight discontinued due to an adverse event, two had a COPD exacerbation, and one withdrew consent

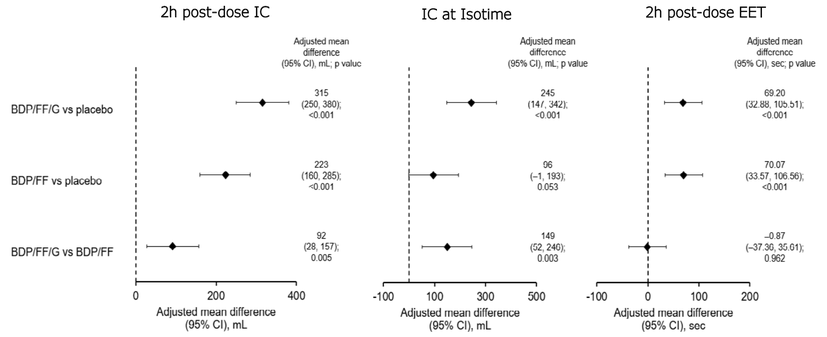
Table 1: Demographics and baseline characteristics (safety set)

Characteristic	Safety Set N=106
Age, years	65.4 (7.2)
Sex, male	66 (62.3%)
Ex-smoker	47 (44.3%)
Current smoker	59 (55.7%)
Post-bronchodilator FEV_1 % predicted	60.60 (12.10)
FRC, % predicted	144.8 (26.0)
GOLD Stage	
1 (FEV_1 ≥80% predicted)	4 (3.8%)
2 (FEV_1 <80% and ≥50% predicted)	75 (70.8%)
3 (FEV_1 <50% and ≥30% predicted)	25 (23.6%)
4 (FEV_1 <30% predicted)	2 (1.9%)
Pre-exercise Inspiratory capacity, L	2.205 (0.804)
Exercise endurance time, min	6.12 (2.94)

Mean and standard deviation or number and percentage are reported

RESULTS

BDP/FF/G showed improvement vs. placebo in both change from baseline in 2-hour post-dose IC [0.315 L (95% CI: 0.250, 0.380), p<0.001] and IC at isotime [0.245 L (95% CI: 0.147, 0.342), p<0.001]. **BDP/FF showed improvement vs. placebo** in 2-hour post-dose IC [0.223 L (95% CI: 0.160, 0.285), p<0.001] and IC at isotime [0.096 L (95% CI: -0.001, 0.193), p=0.053]. **An improvement with BDP/FF/G vs. BDP/FF was observed** in both IC 2-hour post dose [0.092 L (95% CI: 0.028, 0.157), p=0.005] and IC at isotime [0.149 L (95% CI: 0.052, 0.246), p=0.003]. **EET time was similar with the two active treatments.**
All three treatments were generally well tolerated.



In patients with COPD, BDP/FF/GB provided statistically and clinically relevant improvements vs. BDP/FF in static and dynamic hyperinflation, together with an improvement vs. placebo in exercise endurance time. (ClinicalTrials.gov ID: NCT05097014)

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