To evaluate the bronchodilator effect of each dose of IND/GLY/MF compared with salmeterol/fluticasone 50/500 μg b.i.d. in terms of peak FEV1 after 21 days of treatment. All three doses of IND/GLY/MF were significantly more effective than salmeterol/fluticasone 50/500 μg b.i.d. (p<0.0001 for all comparisons).

IND/GLY/MF 150/50/160 µg o.d. (Test) vs. salmeterol/fluticasone 50/500 µg b.i.d. (Ref.):
- Adjusted mean difference: 52.7 mL (95%CI: 32, 73.1)
- p<0.0001

IND/GLY/MF 150/50/80 µg o.d. (Test) vs. salmeterol/fluticasone 50/500 µg b.i.d. (Ref.):
- Adjusted mean difference: 34.9 mL (95%CI: 8, 61.5)
- p=0.009

IND/GLY/MF 150/50/80 µg o.d. (Test) vs.IND/GLY/MF 150/50/160 µg o.d. (Test):
- p=0.136

Exploratory efficacy endpoints: pre-medication evening PEF during a period of 5 min to 4h after the last evening dose of each treatment period.

Primary efficacy results: effect of IND/GLY/MF on peak FEV1

Secondary efficacy endpoints: standardized FEV1/AUC at various time points, and FEV1 measurements over 24 h

Safety

All patients completed the study. Any type of adverse event was reported in 83% of patients who received IND/GLY/MF and 81% of patients who received salmeterol/fluticasone 50/500 μg b.i.d. The most common adverse events (AEs) reported in patients who received the high-dose ICS compared with salmeterol/fluticasone 50/500 μg b.i.d. were cough (11% vs. 8%), headache (8% vs. 1%), and flu-like symptoms (7% vs. 2%).

References