Step-up to High Dose Fluticasone Furoate in Combination With Long-Acting Bronchodilator in Inadequately Controlled Asthma: The CAPTAIN Study

Poster No. 072


Background

In 56% of patients with asthma and inadequate control despite maximum dual therapy, an additional ICS/LABA (FF/VI) strategy might improve control. GSK and Boehringer Ingelheim co-funded a trial to evaluate the safety and efficacy of step-up to FF/VI versus step-up to FF/VI 200/25 mcg in patients inadequately controlled on dual therapy.

Methods

The CAPTAIN study (NCT03603800) was a Phase IIIb, randomized, double-blind, 24-week, parallel-group study investigating the efficacy and safety of once-daily fixed dose dual therapy with FF/VI and step-up therapy with FF/VI doubling to FF/VI 200/25 mcg in patients with asthma inadequately controlled on dual therapy with FF/VI. Patients included were randomized stratified by step-up dose (100/25 vs. 200/25) and concomitant use of oral corticosteroids (yes vs. no). The primary endpoint was trough FEV1 at Week 24 compared with baseline. Safety analyses were performed on all randomized patients (ITT population). Adjusted odds ratios (95% CI) were calculated for the incidence of asthma exacerbations and change in trough FEV1 from baseline to Week 24.

Results

(All data collected post-patient randomization including past-treatment were included in analyses with the exception of Figure 3. *p-value ≤ 0.05; †p-value ≤ 0.01; ‡p-value ≤ 0.001; * *p-value ≤ 0.0001; n=396; n=371; n=374)

Conclusions

This trial demonstrated the step-up dual therapy FF/VI 200/25 mcg may improve FEV1 and asthma control in patients inadequately controlled with ICS/LABA therapy.

References


Presented at the American Academy of Allergy Asthma & Immunology Annual Meeting, Philadelphia, PA, USA, March 13–16, 2020

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