AstraZeneca

STUDY REPORT SUMMARY:

The aim of the study was to evaluate the efficacy of Symbicort® Turbuhaler® (formoterol/budesonide) therapy for asthma in real life conditions. For this purpose we included patients that were treated with Symbicort® Turbuhaler® the »classical« maintenance only treatment approach as well as those treated with the SMART approach. Efficacy was measured by means of asthma control and the number of daily maintenance and reliever inhalations of Symbicort® Turbuhaler®.
Result from the study showed that treatment of uncontrolled asthma with Symbicort® Turbuhaler® is effective with both the SMART regimen as well as the fixed dosage regimen with SABA as required. In both treated groups pulmonary function improved while proportion of uncontrolled asthma decreased over time. In the SMART group, number of additional Symbicort® Turbuhaler® inhalations also decreased over time.

ASTRAZENECA PHARMACEUTICALS:
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FINISHED PRODUCT:
Symbicort® Turbuhaler®

ACTIVE INGREDIENT:
formoterol/budesonide

Study No:
NIS-RSI-SYM 2008/1 NCT00782314

Developmental phase: marketed product

Study Completion Date: July 2009

Date of Report: October 2009

OBJECTIVES:

Evaluating the Symbicort® Turbuhaler® (formoterol/budesonide) maintenance and reliever therapy for asthma in daily practice – an open label non-interventional evaluation of clinical and cost efficacy of Symbicort Turbuhaler 80 µg /4.5 µg or 160 µg /4.5 µg (formoterol/budesonide) maintenance and reliever therapy for asthma in daily practice.

To determine the efficacy of both possible treatment approaches with Symbicort® Turbuhaler®, measured by asthma control.

METHODS:

Only patients diagnosed with asthma and already treated with different Symbicort® Turbuhaler® strengths in line with the relevant SmPCs were allowed to participate in the NIS. The investigator filled out the questionnaires for the initial and the two follow-up visits on regular check-ups.
Based on assumptions that there should be 0.2 asthma worsening/patient/year and that SMART dosing approach is 25% more effective than fixed dosing approach in this respect, the direct statistical evaluation of superiority of SMART dosing was not feasible for Slovenia – more than 600 patients per arm followed-up for 6 months would be needed for statistical analysis using t-test with α=0.05 and β= 0.2. Therefore, only descriptive statistics and graphics were used.
For the analysis of prescribing to different patient subgroups with regards to age, education and year of first diagnosis, Mann-Whitney U-test and Kruskal-Wallis H-test were used.

RESULTS:

The baseline cumulative dose of Symbicort® Turbuhaler® in the SMART group significantly exceeded the baseline cumulative dose in the fixed dosage group, while after 6 months no significant difference was present between the groups. The comparison deliberately did not take into account other medicinal products that were required for asthma management in the fixed dosage group.
This indicates similar long-term rationality of the SMART therapy and the fixed dosage therapy. It is quite probable that therapy with Symbicort® Turbuhaler® according to the SMART regimen might even prove more rational compared to the fixed dosage regimen if the patients were followed for a 12 months instead of only 6 months.

In both groups, improvement of asthma control (as evaluated by the Assessment of Asthma Control Questionnaire) was associated with increased treatment duration. The baseline asthma control was similar in both groups, with a significant improvement observed in the SMART group at follow-up visits.

Pulmonary function improved over time in both groups and differences in FEV1 changes were not significant between groups.

Although educational levels among the groups were not statistically different, a trend was observed toward increasing proportion of SMART users among patients with higher educational level. This is understandable: on one hand it is presumably easier for the health professional to explain the pathophysiology of the early anti-inflammatory action of SMART to such patients; on the other hand these patients are more likely to understand such an explanation easier.

A surprising finding is the large mismatch between evaluation of asthma control by the doctors and evaluation based on the Assessment of Asthma Control Questionnaire. It is

conceivable that doctors do not assess anamnestic data and clinical symptoms adequately and that, concomitantly, they are not paying enough attention to the guiding principles of the Questionnaire.

Based on absence of adverse effects in both groups, it may be concluded that both treatment modalities employed are safe.

The need for additional therapy with an oral corticoid decreased over time.

Treatment of uncontrolled asthma with Symbicort® Turbuhaler® is effective with both the SMART regimen as well as the fixed dosage regimen with SABA as required. In both treated groups pulmonary function improved while proportion of uncontrolled asthma decreased over time. In the SMART group, number of additional Symbicort® Turbuhaler® inhalations also decreased over time.