AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: This non interventional trial was NOT designed to document a specific product.
ACTIVE INGREDIENT:

Study No: NIS-RAT-SYM-2007/1
BE SMART NIS

Developmental phase: marketed
Study Completion Date: 12/2007
Date of Report: final report: 08/2008

OBJECTIVES:

The non-interventional study “be smart” aimed at determining whether an improvement in asthma control can be achieved in patients with moderately severe and severe asthma and poor asthma management by an adaptation of the therapeutic regime. Throughout the observation period the physicians’ freedom to opt for a particular form of therapy was respected. The participating physicians defined a new treatment regime on the basis of the patients’ histories and their status was documented by the patients themselves

METHODS:

The be smart non-interventional study took the form of a questionnaire sent to office-based pulmonologists in the period June to November 2007.
The inclusion criterion for patients with moderately severe and severe asthma was poor asthma control despite maintenance therapy combined with reliever medication. Assessment of asthma control was according to the GINA Guidelines. Throughout the observation period the physicians’ freedom to opt for a particular form of therapy was respected. The participating physicians defined a new treatment regime on the basis of the patients’ histories and their status was documented by the patients themselves. The study began with an initial examination (visit 1) and ended with a final examination (visit 2) after approx. three to six weeks.
At their first visit patients received a treatment diary in which they were asked to document their maintenance and reliever medication as well as the impact of

asthma on their sleep, the number of reliever medications required as well as any asthma-induced functional impairments in daily life.
All variables were evaluated by descriptive statistical methods.

RESULTS:

716 patients were treated and documented over a period of 3 to 6 weeks, on an average visit 2 took place after approximately 37 days. The majority of the physicians opted for the SMART regime, so that 566 patients received this form of treatment.

Pulmonary function

In the patients eligible for evaluation pulmonary function, measured in terms of FEV1 (% of normal value), improved significantly, by an average of 12.5%, compared with the initial value ($p<0.001$).

Frequency of exacerbations

The initial examinations revealed that 77.2% of all patients had undergone treatment because of at least one exacerbation during the year prior to the study. In the observation period of 3 to 6 weeks only 2.4% of patients had to be treated for an asthmatic attack.

Diurnal and nocturnal symptoms, everyday activities and reliever medication

As regards diurnal symptoms such as coughing, shortness of breath and dyspnoea a significant improvement was found in 89% of patients ($p<0.001$).

After treatment for approximately 5 weeks 74% of all patients showed a statistically significant improvement in their capacity to perform everyday activities such as work, school attendance/study, and housework ($p<0.001$).

83% of the study population experienced a significant improvement in terms of undisturbed sleep at night ($p<0.001$).

As regards the need for reliever medication in the last 4 weeks 69% of patients showed a significant reduction of reliever intake ($p<0.001$) in comparison with the initial examination.

Assessment of asthma control by patients and physicians

As assessed by the patients asthma control improved in 86% of the total study population ($p<0.001$).
As assessed by the physicians 93% of the total study population achieved a significant improvement in asthma control ($p<0.001$).

Safety and tolerance

9 of the total of 716 patients (1.3%) showed adverse effects, which were, however, not severe in any of the cases and included transient shivering and irritability, sore throat, skin rash, hoarseness, tachycardia, slight shivering and husky voice, nocturnal tachycardia initially, candida despite careful rinsing and brushing of teeth as well as tremor (mentions refer to one instance each).