AstraZeneca

STUDY REPORT SUMMARY

NIS-RHU-XXX-2011/1

Asthma control study 2011

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No specific study drug
ACTIVE INGREDIENT: N/A
Developmental Phase: Non-Interventional Study
Study Completion Date: 2011 Oct 21 (Last Subject Last Visit)
Date of Report: 2012 Oct 18

OBJECTIVES:

To asses the control level of persistent asthmatic patients in Hungary by ACQ-5

To evaluate the clinical practice in maintaining asthma control level in Hungarian patients

METHODS:

Prospective, multicentre, observational 3 months non-interventional trial using probability methods for assessment of persistent asthmatic patient's asthma control level assessed by ACQ-5 questionnaire

Inclusion criteria: Persistent asthmatic patients above 18 years of age

Exclusion criteria: COPD, bronchiectasia, pulmonary tuberculosis, lung cancer

RESULTS:

The study was undertaken over a three months period with 1465 randomly selected patients; patient who met the inclusion criteria was enrolled to the study; subjects over aged 18 years with a clinical diagnosis of asthma made by a chest physician of differing severity.

In the study a total of 1058 patient's data were analysed, 407(27,8%) had to be excluded from the analysis

Table 1. **Patient Characteristics**

Age	50,87±15,86
% of Females	65,31%

The **average duration of the disease** as 8,98±8,87 years.

The **lung function parameters** at the baseline were as follows:
FEV1: 73,5±17,2
PEF:68,5±17,7
The lung function parameters changed significantly (P<0,0001):
FEV1: 83,5±15,0
PEF: 77,3±17,7

The **ACQ5 score** changed significantly from the baseline (p<0,0001):

ACQ5 score at first visit: 2,34±1,2
ACQ5 score at second visit: 0,77±0,8

The answers to all question of ACQ5 shows a significant (p<0.0001) improvement in the control level of asthma (night time awakenings, asthma symptoms severity in the morning, activity during the day, dyspnoe, and wheezing)
On the first visit 74,4% of patients were not controlled, 14,5% were partially controlled, and only 10,9 % of them were well controlled.
On the second visit 17,1% of patients were not controlled, 19,9% of them were partially controlled, and 62,9% were well controlled based on the ACQ% questionnaire. (Not controlled>1,5, partially controlled 0,75-1,5, well controlled. <0,75)

Asthma medication

before the first visit 40,1% of patients were on combination therapy, 36,7% were on mono ICS, others on leucotriene antagonists, anticholinerg therapy. 48% of all patients got SABA.

After the baseline visit the 72% of the patients were switched to combination therapy consequently at the second visit majority of the patients received combination therapy.

Statistical analysis was done with Wilcoxon rang test.