AstraZeneca

STUDY REPORT SUMMARY

ASTRAZENECA PHARMACEUTICALS

FINISHED PRODUCT: No drug
ACTIVE INGREDIENT: No drug

Study No: NIS-RSE-DUM-2010/1,   NCT number NCT01146392

An investigation of the past 10 years health care for primary care patients with chronic obstructive pulmonary disease (PATHOS)

Developmental Phase: Observational study
Study Completion Date: 21 September 2011
Date of Report: 6 September 2012

OBJECTIVES:

The present retrospective, observational population based study examined the development of the CODP health care structure and the management of patients with COPD in Sweden during 1999 to 2011. The study included longitudinal assessment of the COPD disease, primary health care structure, mortality, co-morbidity, efficacy and safety.

METHODS:

Primary care medical records data from all patients with a COPD diagnosis (ICD-10 J44) at the participating health care centers during 1 January 1999 to 31 December 2009 was linked to data from mandatory Swedish registers – the National Patient Register, Cause of Death Register, and Swedish Prescribed Drug Register.

Index date was defined as the first COPD diagnosis; alternatively, in a cohort analysis, at first prescription of a fixed ICS/LABA (inhaled corticosteroid/long-acting β2 agonist) combination in addition to the COPD diagnosis. Exacerbations were defined as hospitalisations, emergency visits, prescription or oral steroids or antibiotics for COPD. Propensity score matching was done at index date. Analyses were pre-specified in a statistical analysis plan and performed using the SAS software, version 9.2.

RESULTS:

A total of 21,361 patients with COPD were included; 53% females, mean age 68.0 years.

During the 11-year study period, COPD was to a larger degree first diagnosed in primary care (59% in 1999 to 81% in 2009). Simultaneously, the mean age at diagnosis decreased by 7 years, from 73 in 1999 to 66 years at first COPD diagnosis in 2009.

Prescriptions of tiotropium and fixed ICS/LABA combinations increased, while ipratropium, LABA and ICS showed stable and/or decreasing trends. During the same time period, exacerbations decreased from 3.0 to 1.3 exacerbations/patient/year. Diagnosis of co-morbidities increased from index date. Mean life expectancy was 8.3 ± 6.8 years shorter than for the average Swedish population.

In the cohort analysis, 9,893 patients with a fixed ICS/LABA prescription were included (7155 budesonide/formoterol; 2738 fluticasone/salmeterol). Propensity score matching created two similar populations of 2,734 patients per group; covering 19,170 patient years. Compared with fluticasone/salmeterol, B/F was associated with a reduced risk of exacerbations/patient/year rate by 27% (p<0.001). In addition, patients in the fluticasone/salmeterol group had a 73% higher rate of pneumonia diagnoses than those in the budesonide/formoterol group (p<0.001).