STUDY REPORT SYNOPSIS

Finished product: not applicable

Active ingredient: not applicable

Study No. NIS-RRS-XXX-2011/1

Observational study to evaluate the correctness of the use of inhaler device in patients with asthma or chronic obstructive pulmonary disease (COPD)

Developmental phase: IV (non-interventional study)
Study completion date: 10 Mar 2012
Date of Report: 5 Mar 2013

OBJECTIVES:

Primary objective:

- Investigator's evaluation of the correctness of patients' usage of inhaler-turbuhaler device in patients with asthma or chronic obstructive pulmonary disease (COPD) assessed by investigator/pulmonologist.

Secondary objectives:
- Global assessment of disease control, done by investigator. Investigator globally assessed the disease control by one on three categories: 'fully controlled', 'partially controlled', 'uncontrolled', based on global asthma/COPD guidelines.
- Evaluation of patients' perception of the inhaler device and their perspective of symptom control and impact on daily life, by using locally prepared and validated Patient's questionnaire.
- Evaluation of the influence of practical education of the patients (performed by physician and/or nursing staff) on all above parameters/assessments
- Collection of local demographics data in patients with asthma and COPD.

METHODS:

There were three visits (baseline-visit 1; after 4 weeks from baseline-visit 2, and after 12 weeks from baseline-visit 3) with two tools of data records - case report form (CRF) and Patient's questionnaire.

In the CRF investigators recorded:

- Patient demographic/epidemiology data

- Investigator's evaluation of the correctness of the inhaler usage by the patient: evaluation of 7-steps of inhaler-turbuhaler device use (correct-1/incorrect-0) with total score range: 0 (worst)-7 (best)

- 'Global assessment' of the current disease control defined as: 'fully controlled', 'partially controlled' and 'uncontrolled'

Patient's questionnaire addressed:

- Patient's perception of the complexity/simplicity of usage of inhaler device (1 question with answers: simple, complicated, and very complicated)

- The main source of their education on how to use the inhaler device (1 question) – healthcare professionals (HCPs), self-learning, other, none/nobody

- Patients' assessment of symptoms control and quality of life (3 questions). Scoring range for the 3 questions related to symptoms and quality of life: 0 (worst)-12 (best)

RESULTS:

Demographic/epidemiology data: This 3-month observational study was conducted in 9 secondary and/or tertiary centres of Serbia with participation of 66 investigators-specialists (pulmonologists or pneumoftisiologists). They included a total of 312 patients. Mean age of patients was 51.75 years (range 18-81 years), 60.6% of them being males. 74% of patients had diagnosis of asthma, 26% had COPD. The mean duration of primary disease (time from first diagnosis) was 4.26 years for asthma and 9.27 years for COPD patients. The mean time of inhaler-turbuhaler usage was 1.79 years in asthma patients and 1.5 years in COPD patients.

Primary objective:

- **Correctness of inhaler usage assessed by investigator:** Significant improvement of the usage if inhaler device was recorded at visit 3 vs. visit 1 (score results: 6.83 vs. 6.01, $p<0.001$).

Secondary objectives:

- **Global assessment of disease control:** there was significant improvement of disease control at visit 3 vs. visit 1: 'fully controlled' disease was recorded by investigators in 76.8% of patients at visit 3 vs. 52.9% of patients at visit 1 ($p<0.001$). Rate of 'non-controlled' patients decreased from visit 1 to visit 3 (9.6% vs. 3%, $p<0.001$).

- **Evaluation of patients' perception of the inhaler device and their perspective of symptom control and impact on daily life**, by using Patient's questionnaire: The inhaler-turbuhaler usage was described as 'complicated' or 'very complicated' by 9.8% of patients at visit 1, and by 1.7% of patients at visit 3 ($p<0.001$). At visit 3, 98.3% of patients described at the usage of inhaler as 'simple'. Disease symptoms and quality of life, assessed by patients improved from visit 1 to visit 3 (mean score for the 3 questions: 8.66 vs. 10.15, $p<0.001$).

- **Evaluation of the influence of practical education of the patients (performed by physician and/or nursing staff) on the above parameters/assessments:** HCPs are the main 'source' of patient's education for the inhaler use. More devotion of HCPs in improvement of patient education re. inhaler use had resulted in improved usage of inhaler device and consequently better disease control, as described by investigators' global evaluation of disease control (visit 3 vs. visit 1, $p<0.001$), and improvement of symptoms/quality of life, as assessed by patients (visit 3 vs. visit 1, $p<0.001$).