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<b>Study No.:</b> SAM100456	
<b>Title:</b> Pilot study: A Single-Centre, Randomised, Open-Label, Cross Over Trial, Assessing Ease of use, Correctness of use and Patient Preference of <i>Seretide</i> (Salmeterol Xinafoate/Fluticasone Propionate Combination) via the <i>Diskus</i> versus <i>Seretide</i> via the Metered Dose Inhaler in Subjects at Least 55 Years of Age with Persistent Asthma or Chronic Obstructive Pulmonary Disease (COPD) Requiring Combination Therapy.	
<b>Rationale:</b> Salmeterol Xinafoate/Fluticasone Propionate Combination is licensed in Ireland for the treatment of asthma and COPD. It is available in two devices, the <i>Diskus</i> and a chlorofluorocarbons (CFC)-free Metered Dose Inhaler (MDI). For elderly subjects aged 55 and over, the perception is that a dry powder inhaler like the <i>Diskus</i> is less convenient to use than a MDI. This has, however, not been shown to date. This study aimed to compare the <i>Diskus</i> with the MDI in a group of elderly subjects. It was a pilot project to assess the feasibility of performing a study in a larger group of subjects in the future.	
<b>Phase:</b> IV	
<b>Study Period:</b> 5 November 2003 to 17 December 2004.	
<b>Study Design:</b> A single-centre, randomised, open-label, cross-over pilot study.	
<b>Centres:</b> 1 in Ireland.	
<b>Indication:</b> Persistent Asthma or COPD	
<b>Treatment:</b> Salmeterol Xinafoate/Fluticasone Propionate Combination via <i>Diskus</i> versus via the MDI. The total treatment period was six weeks, three weeks on each treatment arm. The protocol did not prescribe a dose; the dose was decided at the discretion of the investigator.	
<b>Objectives:</b> To determine the ease of use, correctness of use and subject preference for the Salmeterol Xinafoate/Fluticasone Propionate Combination via <i>Diskus</i> compared with the MDI in elderly subjects with asthma or COPD.	
<b>Primary Outcome/Efficacy Variable:</b> The primary endpoint was the ease of use determined by a subject completed ease of use questionnaire.	
<b>Secondary Outcome/Efficacy Variable(s):</b> Secondary endpoints included a device specific provider-rated scale for measuring the ability of the subjects to correctly use the device and a subject preference questionnaire. In addition a measure that quantified the amount of teaching required before a subject can use each device correctly was employed.	
<b>Statistical Methods:</b> This was a pilot study. There was no power calculation, and no statistical analysis was performed. A full data analysis was not performed and the data presented was derived from descriptive analyses only. Two populations of subjects were considered: The Intent-to-Treat (ITT) Population consisted of all subjects who were randomised to study drug. All data collected on these subjects were included in the ITT analyses of efficacy, ease of use, preference, correctness-of-use, demography, background characteristics, and safety data. In order to assess device differences in the primary, secondary, and other measures, subjects must have had data collected during both treatment periods. The primary analysis population was the ITT Population.	
<b>Study Population:</b> A subject was eligible for inclusion in this study only if the following criteria applied: Male or non-pregnant female using adequate contraception; at least 55 years of age; a diagnosis of asthma as defined by the Global Initiative for Asthma Guidelines or a diagnosis of COPD as defined by the Global Initiative for Chronic Obstructive Lung Disease Guidelines; and a need, in the opinion of the investigator, for combination treatment with Salmeterol Xinafoate/Fluticasone Propionate combination. A subject was not eligible for inclusion in this study if the following criteria applied: Stability of Asthma/COPD: Hospitalised for an acute exacerbation of asthma/COPD within 3 months of Visit 1. Other Medication for Asthma/COPD: Use of oral, depot or parenteral corticosteroids within 4 weeks of Visit 1 or a need for more than 3 courses of oral, depot or parenteral corticosteroids within 3 months of Visit 1. Other Devices for Asthma/COPD: Historical or current use of the <i>Diskus</i> device.	
<b>Number of Subjects:</b>	
Planned, N	20
Randomised, N	19
Completed, n (%)	17 (89)

Total Number Subjects Withdrawn, n (%)	2 (11)	
Withdrawn due to Adverse Events n (%)	1 (5)	
Withdrawn due to Lack of Efficacy n (%)	0	
Withdrawn for other reasons n (%)	1 (5)	
<b>Demographics</b>		
N (ITT)	19	
Females: Males	14:5	
Mean Age, years (SD)	64.3 (7.6)	
Race, n (%)	Not reported	
<b>Primary Efficacy Results:</b>		
	<b>Diskus</b>	<b>MDI</b>
Ease of use	53% (8/15)	47% (7/15)
<b>Secondary Outcome Variable(s):</b>		
	<b>Diskus</b>	<b>MDI</b>
In-ability to use device correctly	1	2
No teaching required	9	4
Device preference	53% (8/15)	47% (8/15)
<b>Safety Results:</b> The collection period for adverse events (AEs) was defined as the study treatment phase plus pre- or post-treatment events that occurred as a result of protocol-mandated procedures (i.e., invasive procedures, modification of subject's previous therapeutic regimen).		
	All subjects (N=19)	
<b>Most Frequent Adverse Events – On-Therapy</b>		
	<b>n (%)</b>	
Subjects with any AE(s), n(%)	3 (16)	
<b>Serious Adverse Events - On-Therapy</b>		
<b>n (%) [n considered by the investigator to be related to study medication]</b>		
Subjects with non-fatal SAEs, n (%)	0	
Subjects with fatal SAEs, n (%)	0	

**Conclusion:**

This was a feasibility study designed to assess the study methodology. The study was an open-label pilot study and a full data analysis was not performed. Diskus was rated as easier than the MDI to use by 53% of subjects whilst 47% found the MDI easier to use. Three adverse events were reported. No fatal or non-fatal serious adverse events were reported.

**Publications:**

No Publication

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