This document provides a short summary of this study for a general audience. You can find more information in scientific summaries of the study. Links to those summaries are provided at the end of this document.

Study names

Short Title: A study to compare the use of ELLIPTA Inhaler with HandiHaler and DISKUS or HandiHaler and Turbuhaler in patients with chronic obstructive pulmonary disease (COPD).

Full Scientific Title: A randomized, open-label, cross-over, placebo-device study investigating critical errors while using ELLIPTA dry powder inhaler (DPI) as compared to HandiHaler DPI used in combination with either DISKUS DPI or Turbuhaler DPI, in adult patients with Chronic Obstructive Pulmonary Disease (COPD).

Study Number: 206215

Who sponsored this study?

GlaxoSmithKline (GSK)
GSK Clinical Support Help Desk
Website: www.clinicalsupporthd.gsk.com
Email: GSKClinicalSupportHD@gsk.com

General information about the clinical study

When was this study done?

The study started in December 2016 and ended in June 2017.

What was the main reason for conducting this study?

Chronic obstructive pulmonary disease (COPD) is a long-term disease of the lungs that makes it hard to breathe and gets worse over time. For patients with COPD, inhalers are an important part of treatment. An inhaler is a handheld device that is designed to deliver medicine to the lungs.

GSK has developed an inhaler (called ELLIPTA) for patients with COPD. It provides a combination of up to three medicines in one inhaler. The other inhalers included in the study (DISKUS, Turbuhaler and HandiHaler) only have one or two medicines. Patients with COPD, who are required to take three inhaled medicines, must often use two or

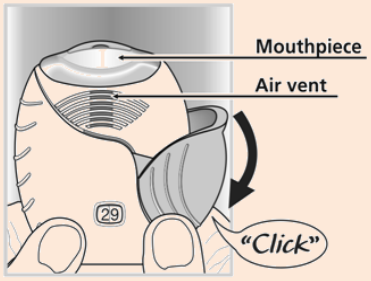
three inhalers. Patients using many different inhalers may be more likely to make mistakes.

What was the main objective of this study?

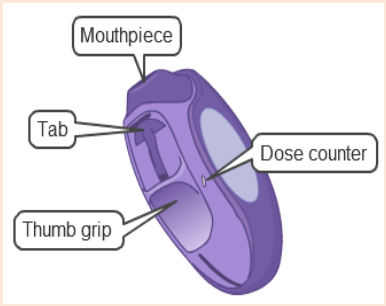
This study compared the number of patients who made at least one critical error while using an inhaler, after reading the how-to-use guide (also called the Patient Information Leaflet). For this study, a critical error was defined as a mistake that could result in the patient receiving little or no medicine.

Which devices were studied?

A. ELLIPTA inhaler



B. DISKUS inhaler



C. Turbuhaler

D. HandiHaler

None of the inhalers used in this study were filled with medicines that would affect the patients' COPD. The patients took their regular medicine and did not receive any extra medicine as part of this study.

How was this study designed?

The patients who took part in this study were placed into one of the following two study groups.

Group 1: ELLIPTA compared to DISKUS and HandiHaler
Group 2: ELLIPTA compared to Turbuhaler and HandiHaler

In each study group, patients used the ELLIPTA inhaler and two other inhalers. Patients were not included in a study group if they had used any of the inhalers in the past two years.

Which patients were included in this study?

Studies have a list of requirements for patients who can enrol (inclusion criteria) and those who can't (exclusion criteria). For this study, the main inclusion and exclusion criteria are listed below.

Main Inclusion Criteria

Men and women were included in the study if they:

- Had COPD.
- Were current or former smokers.
- Were at least 40 years old.
- Were taking inhaled medicines for COPD for at least 4 weeks before starting this study and were unlikely to change them for 4 weeks after starting the study.

Main Exclusion Criteria

Men and women were excluded from the study if they:

- Had asthma.
- Were unable to read or take verbal instructions.

For more detailed information about the patients included in this study, see the scientific summary on the GSK Study Register (see link provided at the end of this document).

The table below shows the patients who were included in the study.

Patients included in the study		
	Group 1: ELLIPTA compared to DISKUS and HandiHaler 80 patients	**Group 2: ELLIPTA compared to Turbuhaler and HandiHaler 79 patients**
Gender - Number of patients (percent)		
Female	39 (49%)	37 (47%)
Male	41 (51%)	42 (53%)
Age - in years		
Range	48 to 82	48 to 92
Average	64	66

Where was this study done?

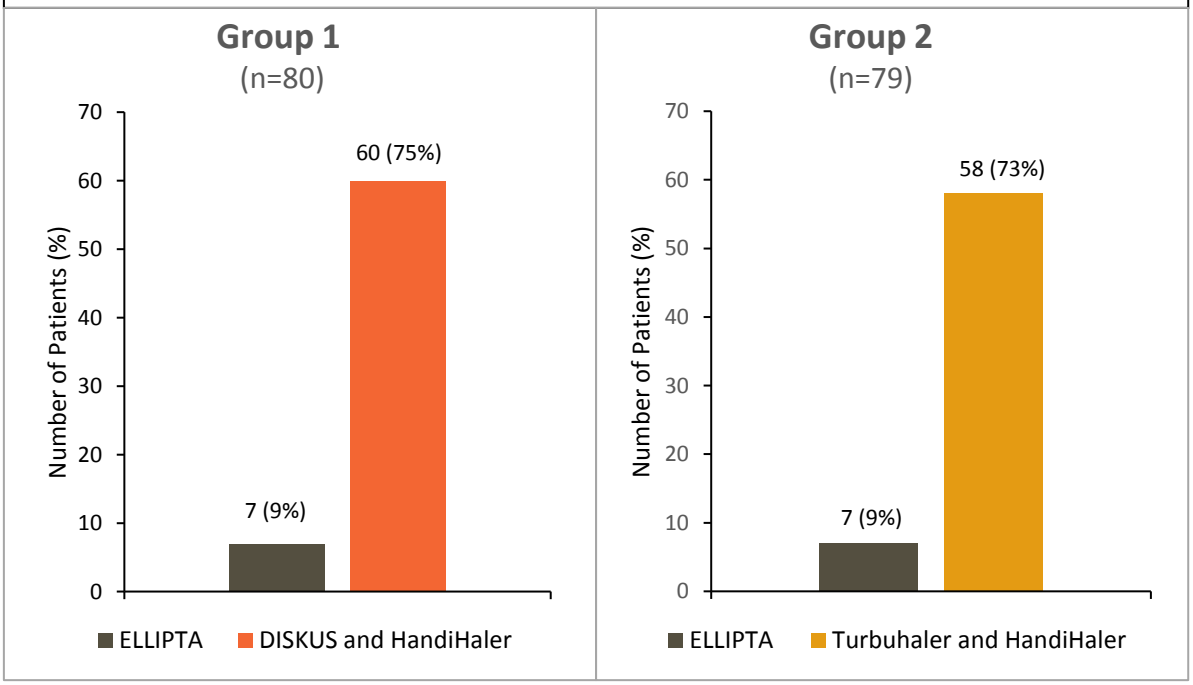
The study sites were located in two countries. A total of 122 patients from the Netherlands and 37 patients from the United Kingdom were included in this study.

What were the overall results of the study?

Each patient read the how-to-use guide for each inhaler before using the inhaler. A study doctor observed the patient and looked for any mistakes. If a patient made a mistake, the study doctor showed them the correct way to use the inhaler. The patient was asked to use the inhaler again, and the study doctor recorded any further mistakes. The study doctor could show the patient how to use the inhaler up to two times. The study doctor noted all the mistakes.

After reading the how-to-use guide, fewer patients made mistakes that were considered critical errors when using the ELLIPTA inhaler compared with the other inhalers in both study groups (see figure below). These differences were statistically significant. This means that the difference was not likely due to chance alone.

Number and percentage of patients who made at least one critical error after reading the how-to-use guide



What were the side effects?

Study doctors collect information about the safety of study treatments. Any medical events including symptoms reported by patients in the clinical study are called adverse events. These adverse events can be found in the scientific summary (see link provided at the end of this document).

Only one adverse event of cuts on both thumbs (laceration) was reported in Group 1. The study doctor believed the event was caused by use of an inhaler (study treatment). The adverse event was not life threatening; did not require hospitalisation; nor did it result in permanent damage.

No adverse events were reported in Group 2.

How has this study helped patients and researchers?

The results of this study will help doctors understand which inhalers are easier for patients to use with less mistakes. Fewer mistakes could help patients breathe more easily.

Are there plans for further studies?

Other studies of the ELLIPTA inhaler in patients with COPD are currently planned and some are ongoing. The results of these studies will also be available on the GSK Study Register.

Where can I find more information about this study?

Clinical studies have unique study numbers that are included in publications and other information about the study. The unique study numbers associated with this study are shown below with internet links to scientific summaries and other information.

The scientific summaries include more details about the requirements for study enrolment, the study visit schedule, results from other endpoints, and more detailed information about adverse events.

Organization	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02982187
GlaxoSmithKline (GSK)	www.gsk-clinicalstudyregister.com	206215

For readers of this document in printed form, the websites that go with the internet links above are
https://www.clinicaltrials.gov/ct2/show/NCT02982187?term=NCT02982187&rank=1
https://www.gsk-clinicalstudyregister.com/search/?study_ids=206215

Your doctor can help you understand more about this study and the results. You should not make changes to your care based on the results of this or any single study. Keep taking your current treatment unless instructed by your doctor.

We would like to thank the patients who contributed to this study. The results of this study will help answer scientific questions about treating patients with COPD.

The content for this document was finalised by GSK on 5th June 2018. The information in this summary does not include additional information available after this date.