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

Study names

Short Title: A study to see how the Connected Inhaler System affected adherence to Relvar/Breo Ellipta treatment in patients with poorly controlled asthma.

Full Scientific Title: An open label, randomised, parallel group clinical study to evaluate the effect of the Connected Inhaler System on adherence to Relvar/Breo Ellipta therapy, in asthmatic subjects with poor control.

Study Number: 207040

Who sponsored this study?

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

General information about the clinical study

When was this study done?

The study started in January 2018 and ended in January 2019.

What was the main reason for this study?

Asthma is a long-term condition of the airways. When the airways are swollen and inflamed, they become narrow. This narrowing can cause coughing, wheezing, chest tightness and shortness of breath.

For patients with asthma, inhalers are an important part of treatment. An inhaler is a handheld device that delivers medicine(s) to the lungs. For any treatment to work well, patients must take it as directed by their doctor. This is called adherence. Due to the

long-term nature of asthma, patients can have low adherence to treatment that may lead to poor control of asthma symptoms.

How was this study designed?

To monitor patients' adherence to treatment, all inhalers used in this study had a sensor clipped on to them. These sensors recorded the time and date when the patients used their inhalers. This information could be viewed by the patients on an app installed on their smartphone and by the study doctor or nurse on their computer. Together, the sensors, the app, and the computer system, are called the Connected Inhaler System (CIS).

The main objective of this study was to see how the use of CIS affected poorly controlled asthma patients' adherence to their Relvar/Breo Ellipta treatment.

Which medicines and devices were used in the study?

Before starting the study, patients were asked to replace their previous asthma treatment (if different) with Relvar/Breo Ellipta.

All patients received Relvar/Breo Ellipta inhaler, with the sensor clipped on it, to be used once daily. This inhaler contained:

- fluticasone furoate (an inhaled corticosteroid [ICS], a medicine that reduces swelling and irritation in the lungs) and,
- vilanterol (an inhaled long-acting beta agonist [LABA], a medicine that relaxes and opens the airways in the lungs).

Patients were prescribed another inhaler, with a sensor clipped on it, containing salbutamol (a medicine that relaxes and opens the airways in the lungs), to use if their asthma symptoms worsened.

Patients with poorly controlled asthma were put into one of the five groups by chance (randomisation). The five groups were based on the inhaler information shared and who could see that information, see figure below.

Study groups				
Group	Relvar/Breo Ellipta inhaler		Salbutamol inhaler	
	Information shared with		Information shared with	
	Patient	Study doctor or nurse	Patient	Study doctor or nurse
Group 1				
Group 2				
Group 3				
Group 4				
Group 5	No information was shared with patient or study doctor or nurse			

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.

Men and women with asthma were included in the study if they:

- Were at least 18 years old.
- Were taking fixed dose of an ICS and a LABA for three months before starting the study.
- Had poorly controlled asthma before starting the study.
- Had their own smartphone, which was suitable to run the app.

Men and women were excluded from the study if they had:

- A history of life-threatening asthma that required hospitalisation within six months before study start.
- Chronic obstructive pulmonary disease.
- Infection of the lower respiratory tract within the week before starting the study.
- Other respiratory diseases such as tuberculosis or lung cancer.
- Any other disease that the study doctor thought would affect the results of the study.

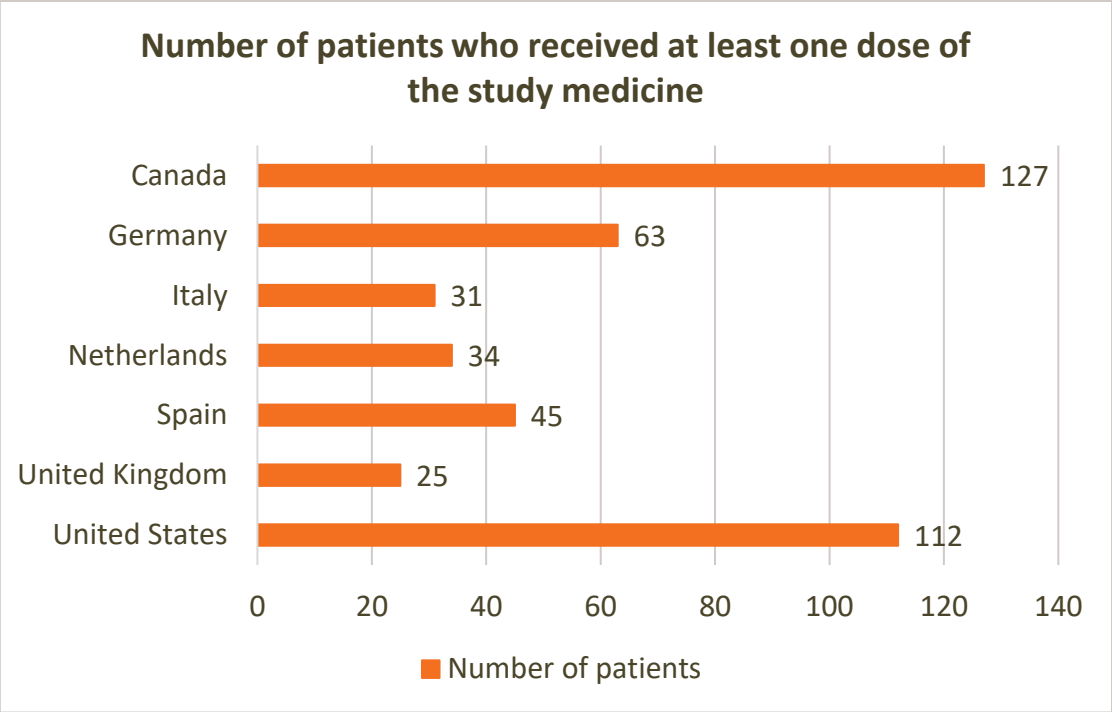
A total of 437 patients received at least one dose of the study medicine. The table below shows the gender and age of these patients.

Patients who received at least one dose of the study medicine					
	Group 1 87 patients	**Group 2 88 patients**	**Group 3 88 patients**	**Group 4 88 patients**	**Group 5 86 patients**
Gender - Number of patients (percent)					
Female	64 (74%)	54 (61%)	59 (67%)	60 (68%)	47 (55%)
Male	23 (26%)	34 (39%)	29 (33%)	28 (32%)	39 (45%)
Age - in years					
Range	19 to 76	18 to 86	20 to 83	18 to 79	19 to 75
Average	47	47	48	48	47

For more detailed information about the patients included in this study, see the scientific results summaries (links to those summaries are provided at the end of this document).

Where was this study done?

Study sites were in seven countries.



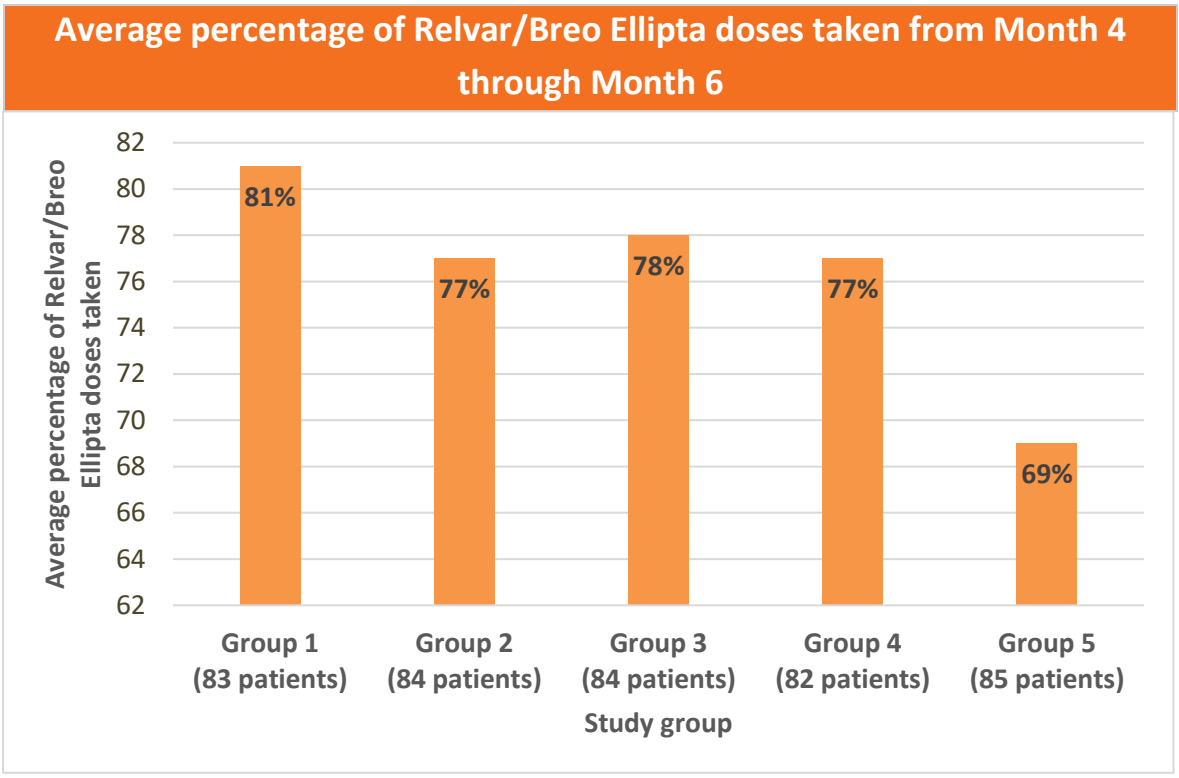
What were the overall results of the study?

The main focus of the study was to compare patients' daily adherence between Group 1 and Group 5, from Month 4 through Month 6. Patients' daily adherence was measured as the average percentage of doses of Relvar/Breo Ellipta treatment taken between this period.

The number of doses of Relvar/Breo Ellipta treatment taken by each patient were recorded by the sensor. The percentage of doses taken by the patient was calculated based on the number of expected doses. These percentages were combined and averaged for each group.

Out of the 437 patients, the average percentage of doses taken could be calculated for 418 patients who were still in the study from Month 4 through Month 6.

The results are shown in the figure below.



The average percentage of Relvar/Breo Ellipta doses taken by patients in Group 1 was 12% higher compared with Group 5. This means daily adherence to Relvar/Breo Ellipta treatment was better when the information about inhaler use was shared with the patient and the study doctor or nurse (Group 1) than when the information was not shared with either (Group 5). There was also better adherence in the other groups (Groups 2, 3, and 4) when information about inhaler(s) use was shared compared with when information about inhaler use was not shared (Group 5).

More information about the study results is available in the scientific results summaries (links to those summaries are provided at the end of this document).

What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a medicine. Study doctors record these events. A summary of all these events can be found in the scientific results summaries (links to those summaries are provided at the end of this document).

If the study doctor thinks that the event was caused by the study medicine, they record this as a possible side effect (adverse reaction).

In this summary, “side effects” refer to those events that the study doctor thinks may have been caused by Relvar/Breo Ellipta treatment. The side effects in this summary may be different to those in the Informed Consent or other documents related to the Relvar/Breo Ellipta treatment.

One patient in Group 5 reported a serious side effect of pneumonia. No patients in any other treatment group reported serious side effects.

Two patients (2%) in Group 1 reported a non-serious side effect of yeast infection in the mouth. No other non-serious side effects were reported by two percent of patients or more in any treatment group.

How has this study helped patients and researchers?

The results from this study showed that using a CIS improved patients’ adherence to their Relvar/Breo Ellipta treatment. Side effects reported in this study were limited.

Are there plans for further studies?

No further studies on CIS in patients with asthma are planned at this time.

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.

Organisation	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2017-002266-45[1]
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03380429[2]

Your doctor can help you understand more about this study and the results. Speak to your doctor about the treatment options available in your country. 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 asthma.

The content for this document was finalised by GSK on the 6th of December 2019. The information in this summary does not include additional information available after this date.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-002266-45

[2] https://clinicaltrials.gov/ct2/show/NCT03380429