

This document provides a short summary of this study for a general audience. You can find more information in the scientific summary of the study. A link to the summary is provided at the end of this document.

Study names

Short Title: A study to assess the correct use and ease of use of the Ellipta inhaler in children with asthma.

Full Scientific Title: An open-label study to evaluate correct use and ease of use of the Ellipta Dry Powder Inhaler in paediatric patients currently receiving inhaled therapy for treatment of their asthma.

Study Number: 206924

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 June 2018 and ended in December 2018.

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. GSK has developed an inhaler, called Ellipta, for patients with asthma.

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For any treatment to work well, patients should take it as directed by their doctor. One of the reasons for the worsening of asthma symptoms is the incorrect use of an inhaler. Incorrect use leads to the delivery of a lower than expected dose of inhaled medicine(s) in the lungs that may lead to poor control of asthma.

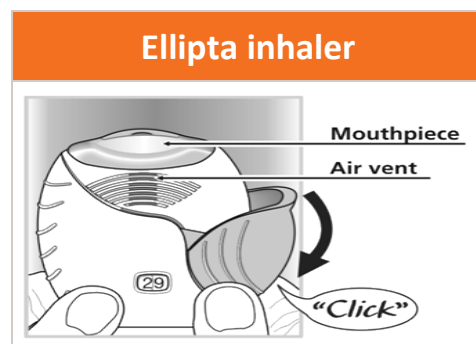
What was the main objective of this study?

This study assessed the percentage of children from two different age groups, who used the Ellipta inhaler correctly after four weeks and rated it easy to use. For this study, the correct use of the inhaler meant that the children avoided making mistakes that could result in receiving little or no medicine.

Which device was studied?

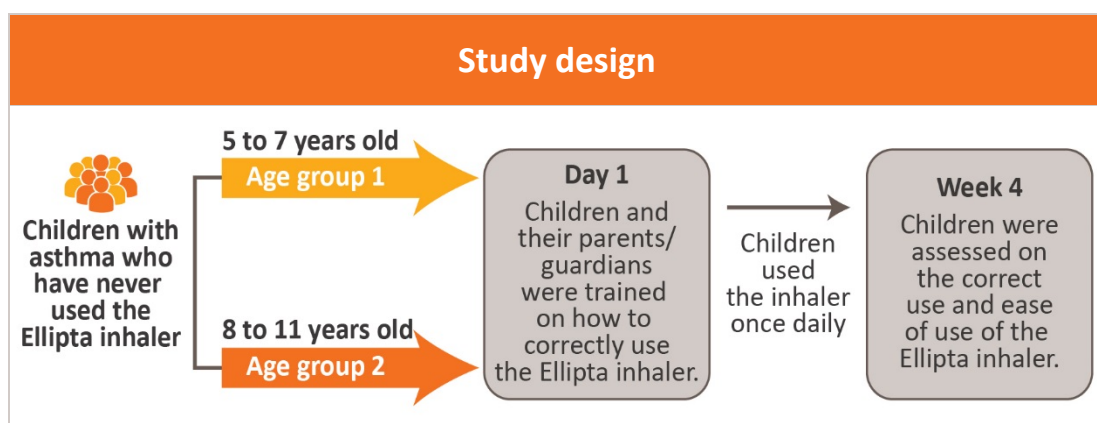
In this study, each child received an Ellipta inhaler filled with placebo (no active medicine).

Children took their regular asthma medicine(s) and did not receive any extra medicine as part of this study.



How was this study designed?

Children were put into one of the two groups based on their age (see figure below).



Which children 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.



Children were included in the study if they:

- Were between 5 to 11 years of age at the start of the study.
- Had been diagnosed with asthma for at least six months before starting the study.
- Had been receiving asthma treatment for three months before starting the study.
- Had never been trained in the correct use of or used the Ellipta inhaler before starting the study.



Children were excluded from the study if they had:

- Other lung diseases such as tuberculosis.
- Any medical condition that the study doctor thought would affect the results of the study.
- Respiratory tract infection within a week of starting the study.
- Worsened asthma symptoms that required hospitalisation or use of corticosteroids (a medicine that reduces inflammation) in the three months before starting the study.

A total of 222 children were included in this study. The table below shows the gender and age of these children.

| Children who were included in this study | | |
|--|----------------------------|-----------------------------|
| | Age group 1 88 children | Age group 2 134 children |
| Gender - Number of children (percent) | | |
| Girls | 41 (47%) | 48 (36%) |
| Boys | 47 (53%) | 86 (64%) |
| Age - in years | | |
| Range | 5 to 7 | 8 to 12 |
| Average | 6 | 10 |

For more detailed information about the children included in this study, see the scientific results summary (a link to the summary is provided at the end of this document).

Where was this study done?

The study sites were located in two countries. A total of 65 children from Canada and 157 children from the United States were included in this study.

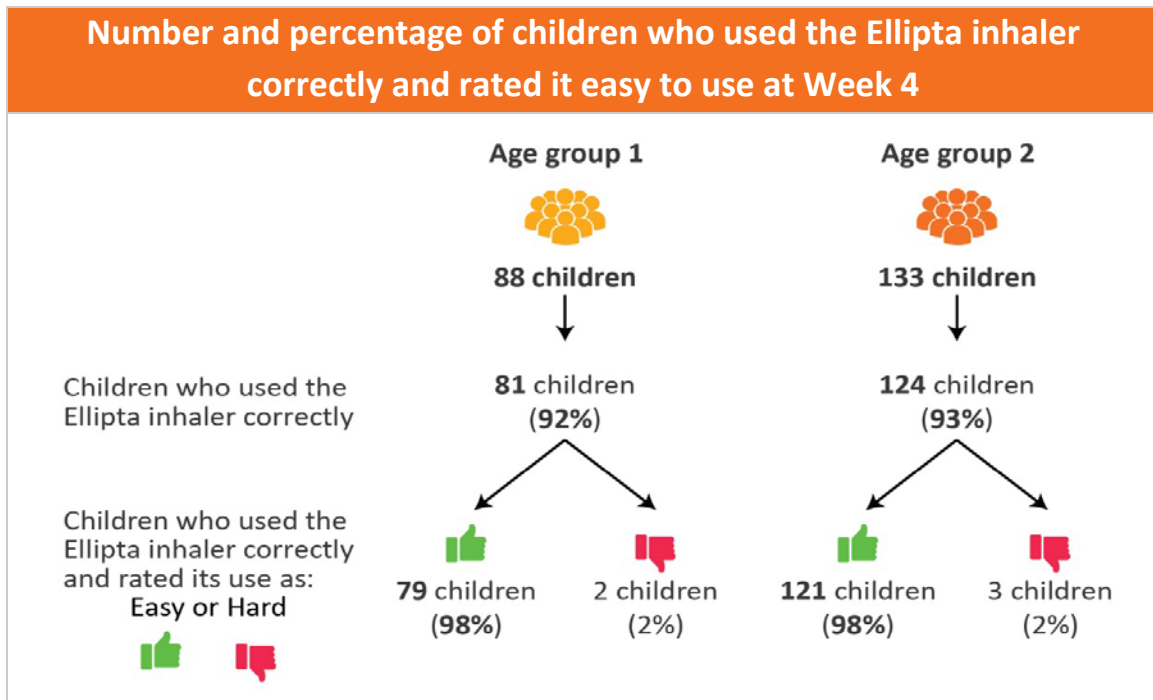
What were the overall results of the study?

Children and their parents/guardians were shown how to correctly use the Ellipta inhaler at the study clinic on Day 1. Each child then used the inhaler while the study doctor or nurse watched. If the child made a mistake, the study doctor or nurse showed the correct way to use the inhaler. The parents/guardians could also guide the child to use the inhaler correctly. Children then used the inhaler once daily at home for 4 weeks.

Children returned to the study clinic at Week 4. Each child was asked to fill a survey to rate if the Ellipta inhaler was easy or hard to use. The study doctor or nurse then watched to see if the child used the inhaler correctly. The percentage of children who

used the Ellipta inhaler correctly, without any help, was calculated. Among the children who used it correctly, the percentage of children who rated the Ellipta inhaler easy to use was also calculated.

In age group 2 (8 to 11 years), one child out of 134 children did not continue in the study until Week 4. Results are shown for 221 children in the figure below.



After 4 weeks of Ellipta inhaler use, more than 90% of the children from both age groups used the inhaler correctly. Of these, 98% of the children rated it easy to use in both age groups.

More information about the study results is available in the scientific results summary (a link to the summary is 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 summary (a link to the summary is 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 the placebo. The side effects in this summary may be different to those in the Informed Consent or other documents related to the study inhaler.

No children reported serious side effects in this study.

No children in age group 1 (5 to 7 years) reported non-serious side effects. In age group 2 (8 to 11 years), one child (less than 1%) out of 134 children had a non-serious side effect of cough.

How has this study helped patients and researchers?

This study showed that the percentage of children who used the Ellipta inhaler correctly and found it easy to use after four weeks was similar between the two age groups.

Are there plans for further studies?

Other studies of the Ellipta inhaler in patients with asthma are ongoing.

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 number associated with this study is shown below with an internet link to the scientific summary and other information.

The scientific summary includes 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 |
|---|--|--|
| United States National Institutes of Health (NIH) | www.clinicaltrials.gov | NCT03478657 ¹ |

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

¹<https://clinicaltrials.gov/ct2/show/NCT03478657>

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 13th of December 2019. The information in this summary does not include additional information available after this date.