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 learn about the effect of fluticasone furoate on growth rate in children with asthma who had not reached puberty.

Full Scientific Title: A multicentre, randomised, double-blind, placebo-controlled, parallel-group study to evaluate the effects of a one-year regimen of orally inhaled fluticasone furoate 50 mcg once daily on growth velocity in prepubertal, paediatric subjects with asthma.

Study Number: 114971

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 October 2016 and ended in June 2021.

What was the main reason for this study?

Asthma is a long-term condition in which the airways in the lungs get inflamed and become narrow. This narrowing can cause coughing, wheezing, chest tightness, and shortness of breath.

Inhaled corticosteroids are among the most common medicines used to treat asthma in children. They reduce inflammation in the lungs and lessen asthma symptoms. However, they can slow down growth.

The medicine given in this study was an inhaled corticosteroid called fluticasone furoate. It was used through an inhaler, a handheld device that delivers medicine directly to the lungs.

Fluticasone furoate had shown to control asthma symptoms in children who were at least 12 years old. Children with asthma who had not reached puberty took part in this study. Puberty is the time in life when a boy or girl becomes sexually mature.

Researchers wanted to learn if fluticasone furoate slowed down the growth in these children when treated for one year. They also assessed the safety of this medicine.

Which medicines were studied?

At the start of the treatment period, participants were included in one of the following two treatment groups by chance (randomisation).

- Fluticasone furoate
- Placebo (no active medicine)

Participants received fluticasone furoate 50 micrograms (mcg) or placebo through an inhaler, once daily in the morning for one year. Neither the participants and their parents, nor the study doctor knew which treatment the participants received. This is called a double-blind study. Participants were also given an additional inhaler, which contained another medicine, to be used as needed if their symptoms worsened.

Participants also took montelukast tablets once daily in the evening throughout the study. It is a medicine used to control and prevent asthma symptoms.

Which participants took part in this study?

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

Participants were included in the study if they:

- Were boys between five to nine years of age or girls between five to eight years of age, with set height and weight requirements.
- Had asthma for at least six months before study start.
- Had well-controlled asthma.
- Used at least one course of corticosteroid for their asthma in the year before study start.

Participants were excluded from the study if they:

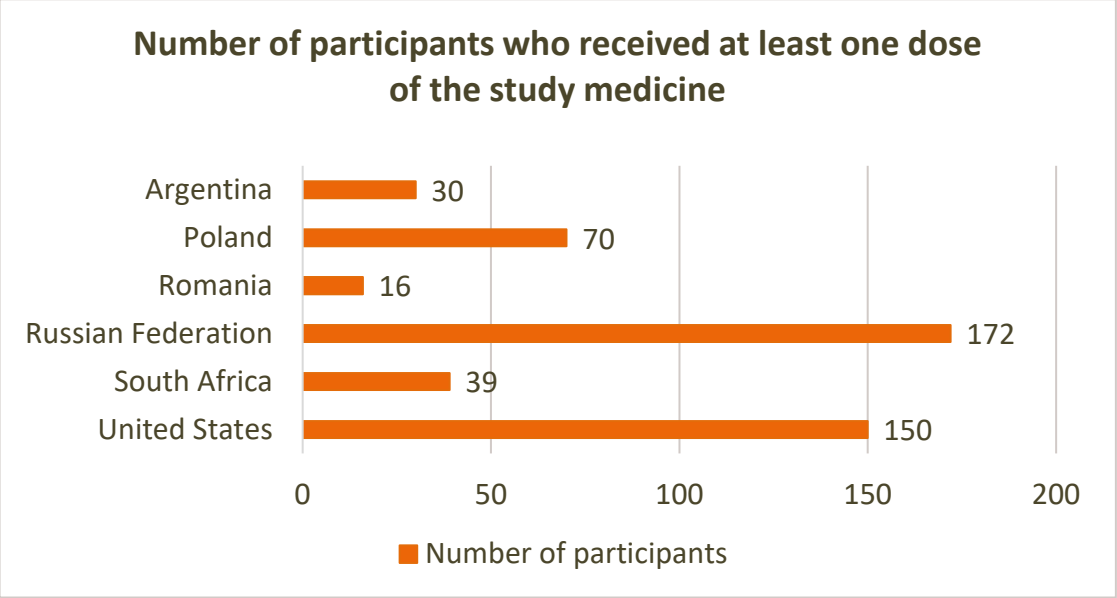
- Had any condition or used any medicines that affect growth rate.
- Showed early signs of sexual maturity.
- Were unable to stand due to illness or disability.
- Had worsening of asthma symptoms.
- Had any other disease(s), condition(s), or taken any treatment(s) that the study doctor thought would affect the results of the study.

Overall, 477 participants received at least one dose of the study medicine. The study included 299 boys (63%) and 178 girls (37%). The average age was six years. The youngest participant was four years old and the oldest participant was nine years old.

For more detailed information about the participants 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 six countries.



What were the main results of the study?

Study doctors recorded each participant's height using a device called a stadiometer, over the one year of treatment.

The main objective of the study was to compare participants' growth rate over the one-year treatment period, between the two treatment groups. Researchers calculated growth rate as the increase in height in centimetres per year (cm/yr).

Growth rate was calculated for the 457 participants whose height was recorded at least three times during the one-year treatment period. Results are shown in the table below.

Average growth rate over the one-year treatment period		
	Fluticasone furoate 231 participants	**Placebo 226 participants**
Average growth rate (cm/yr)	5.9	6.1

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 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).

The side effects in this summary may be different to those listed in the Informed Consent or other documents related to the study medicine.

In blinded studies, the study doctor does not know which study medicine the participant is taking. In some cases, side effects will be assigned to placebo.

The side effects in this summary have been reported during the one-year treatment period.

No serious side effects were reported.

A non-serious side effect of yeast infection in the mouth and throat was reported by one participant in the fluticasone furoate group. No non-serious side effects were reported by any participant in the placebo group.

How has this study helped participants and researchers?

The study showed that the effect of fluticasone furoate on growth rate in children with asthma who had not reached puberty was small during the one-year treatment period. Side effects reported in the study were limited and non-serious.

Are there plans for further studies?

Other studies of fluticasone furoate in children with asthma have been completed and one study is ongoing. No further studies 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.

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 and Website	Study Number
European Medicines Agency (www.clinicaltrialsregister.eu)	2016-002551-22[1]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT02889809[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 participants who contributed to this study. The results of this study will help answer scientific questions about treating children with asthma.

The content for this document was finalised by GSK on 23 February 2022. The information in this summary does not include additional information available after this date.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2016-002551-22
[2] https://clinicaltrials.gov/ct2/show/NCT02889809