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 how well two different doses of fluticasone furoate nasal spray work and how safe they are in Chinese children with allergic rhinitis.

Full Scientific Title: A Randomized, Doubled-Blind, Placebo-Controlled, Multicentre Study to Evaluate the Efficacy and Safety of Once-Daily, Intranasal Administration of Fluticasone Furoate Nasal Spray 55 µg and 110 µg for 4 Weeks in Chinese Paediatric Subjects Ages 2 to 12 years with Allergic Rhinitis.

Study Number: 201492

Who sponsored this study?

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

General information about the study

When and where was this study done?

The study started in September 2015 and ended in October 2017. All study sites were in China.

What were the reasons for conducting this study?

An allergic reaction is the body's response to foreign substances called allergens. Allergic rhinitis is a type of allergic reaction that affects the nose. It is caused when people breathe in substances like pollen, dust, mould or flakes of skin from certain animals. Allergic rhinitis causes symptoms, such as:

- Runny, stuffy nose.
- Sneezing.
- Itchy nose and eyes.
- Red, burning and watery eyes.

Fluticasone Furoate Nasal Spray (FFNS) is a corticosteroid These medicines reduce swelling and soreness in the nose which are often caused by allergic rhinitis. These medicines are sprayed into the nose as a fine mist. FFNS is approved in many countries to treat allergic rhinitis in children and adults. In this study, the study doctors wanted to see if different doses of FFNS reduced the symptoms of allergic rhinitis in Chinese children. They also studied the safety of FFNS in these children.

Which medicines were studied in this study?

Children were included in one of the following three treatment groups by chance (randomisation).

- Placebo (containing no active medicine)
- FFNS 55 µg once daily
- FFNS 110 µg once daily

Instructions on how to use the nasal spray correctly were given to the children and their parents. The children (on their own or with the help of their parents) sprayed the medicine in their nose each morning for four weeks. The children, their parents and study doctors did not know which of the three medicines were given to each child. This is called a double-blind study.

Which patients took part 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

Children were included in the study if they:

- Had been diagnosed with allergic rhinitis.
- Were between two to twelve years of age.

Main Exclusion Criteria

Children were excluded from the study if they had:

- Any medical condition that the study doctor thought would affect the results of the study.
- Asthma (except if it was very mild).
- A severely blocked nose, making breathing difficult.
- Regular nosebleeds.
- Any infection, such as yeast infection in the nose and throat.

A total of 358 children between two to twelve years of age (average age of seven years) took part in this study. The table below shows the number of girls and boys in each of the three treatment groups.

Gender of children included in the study			
	Placebo Out of 120 children	**FFNS 55 µg Out of 119 children**	**FFNS 110 µg Out of 119 children**
Girls	42 (35%)	38 (32%)	32 (27%)
Boys	78 (65%)	81 (68%)	87 (73%)

For more detailed information about the children included in this study, see the scientific summary on the ClinicalTrials.gov website (see link provided at the end of this document).

What were the overall results of the study?

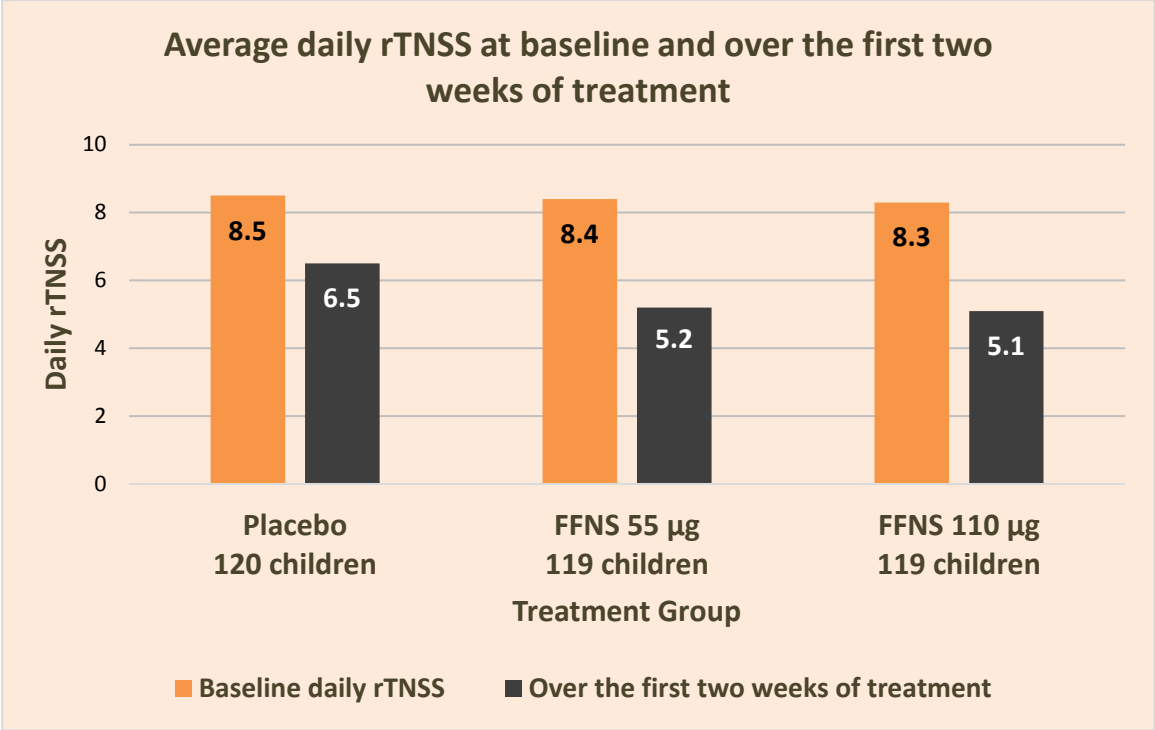
Parents of the children who took part in the study, rated four of their children's symptoms:

- Sneezing.
- Runny nose.
- Stuffy nose.
- Itching in the nose.

Symptoms were scored once in the morning (before using the nasal spray) and once in the evening (12 hours after using the nasal spray) as:

- None (0).
- Mild (1).
- Moderate (2).
- Severe (3)

The total nasal symptom score is the combined score of the above four symptoms, with a maximum score of 12. An average of the morning and evening scores was calculated for each patient. This was called the daily reflective total nasal symptom score (rTNSS). The graph below presents the average daily rTNSS calculated at the start of the study (baseline) and over the first two weeks of treatment.



A decrease in daily rTNSS means an improvement in nasal symptoms. Over the first two weeks of treatment, study doctors observed a decrease in average daily rTNSS in all the three treatment groups. In the placebo group, the average daily rTNSS decreased by two. The average daily rTNSS decreased by 3.2 in both FFNS groups. This decrease in both FFNS groups was statistically significant compared to the children who received placebo. Statistically significant means that the difference was not likely due to chance alone.

What were the side effects?

Study doctors collect information about the safety of study medicines. 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 on the ClinicalTrials.gov website (see link provided at the end of this document).

The study doctors record if they think any of these events may be caused by the medicine. If the study doctor believes that the event was caused by the medicine, they record this adverse event as a possible side effect. In a clinical study, these are called **adverse reactions**. A **serious adverse reaction** is an adverse reaction that is life threatening, requires hospitalisation or results in death or permanent damage. In blinded studies, the study doctor does not know which study medicine the patient is taking. In some cases, adverse reactions may be related to placebo.

This plain language summary describes those side effects (adverse reactions including serious adverse reactions) recorded by study doctors.

No serious adverse reactions were reported in this study.

The table below shows the adverse reactions reported by two or more children in any treatment group.

Non-serious adverse reactions reported by two or more children in any treatment group			
	Placebo Out of 120 children	**FFNS 55 µg Out of 119 children**	**FFNS 110 µg Out of 119 children**
Nosebleed	14 (12%)	6 (5%)	9 (8%)
Damage to the lining of the nose	3 (3%)	1 (less than 1%)	0
Cold	2 (2%)	0	1 (less than 1%)
Fever	2 (2%)	0	0
Cough	1 (less than 1%)	2 (2%)	3 (3%)
Swelling of sinuses around the nose	1 (less than 1%)	4 (3%)	1 (less than 1%)

For further information about safety, including details about the adverse events that study doctors did not think were related to the study medicine, please see the scientific summary on the ClinicalTrials.gov website using the link at the end of this document.

How has this study helped patients and researchers?

This study helped researchers better understand how FFNS works in Chinese children with allergic rhinitis.

Are there plans for further studies?

There are no plans for further studies of FFNS in children with allergic rhinitis. One study of FFNS in Chinese adult patients with allergic rhinitis is 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 are shown below with an internet link to 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.

Organization	Website	Study Number
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT02424539

For readers of this document in printed form, the website that goes with the internet link above is

https://clinicaltrials.gov/ct2/show/study/NCT02424539

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

We would like to thank the children and their parents who contributed to this study. The results of this study will help answer scientific questions about treating children with allergic rhinitis.

The content for this document was finalised by GSK on 28th September 2018. The information in this summary does not include additional information available after this date.