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 assess how well GSK3772847 works and how safe it is in patients with moderate to severe asthma with allergic fungal airway disease.

Full Scientific Title: A double blind (sponsor open) placebo-controlled, stratified, parallel group study to evaluate the efficacy and safety of repeat doses of GSK3772847 in participants with moderate to severe asthma with allergic fungal airway disease.

Study Number: 207972

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 April 2018 and ended in January 2020. Study enrolment ended early as it was too difficult to enrol enough patients in a timely manner.

What was the main objective of this study?

Asthma is a long-term condition of the airways. When the airways are inflamed, they become narrow. This narrowing can cause coughing, wheezing, chest tightness, and shortness of breath. Patients with moderate to severe asthma with allergic fungal airway disease (AFAD) are allergic to certain fungi that can trigger or worsen asthma.

GSK3772847 is a medicine that may reduce inflammation. Patients with moderate to severe asthma with AFAD took part in this study. Researchers wanted to see how well

GSK3772847 works when added to regular asthma treatment compared with regular asthma treatment alone. Researchers also studied the safety of GSK3772847.

Which medicines were studied?

Patients were placed in one of the following two treatment groups by chance (randomisation):

- GSK3772847
- Placebo (no active medicine)

Neither the patients nor the study doctors knew who was receiving which treatment. This is called a double-blind study.

During the study, patients continued taking their regular asthma treatment. Patients received study medicine directly through a vein on Day 1, Week 4, and Week 8 of the 12-week treatment period.

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 moderate to severe asthma were included in the study if they:

- Were at least 18 years old.
- Met the required test scores to assess lung function and inflammation.
- Met the required blood eosinophil (a type of white blood cell) levels.
- Were taking regular asthma treatment for at least four months before starting the study.
- Had AFAD with at least one severe episode of worsening of asthma within one year before starting the study.

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

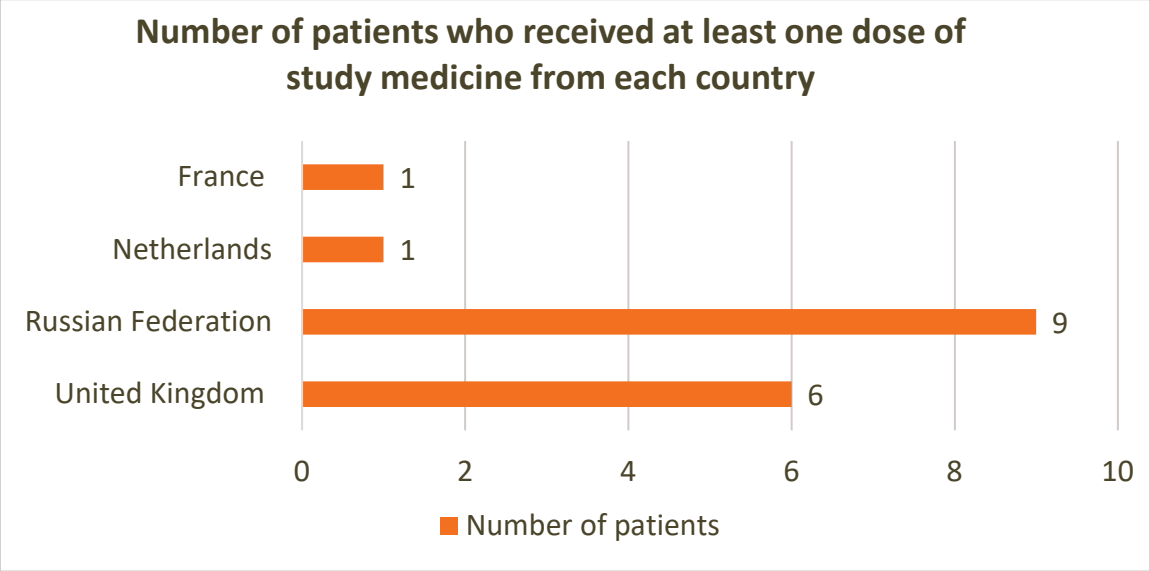
- Lung diseases such as cystic fibrosis, pneumonia, or chronic obstructive pulmonary disease.
- Any other disease that increases blood eosinophil levels.
- A serious infection within eight weeks before starting the study or any long-term infection (except lung infection).
- Heart diseases.
- Any other disease(s) or treatment(s) that the study doctor thought would affect the results of the study.

Of the 115 patients considered for enrolment, only 17 patients received at least one dose of study medicine. The study included 12 (71%) men and 5 (29%) women. The average age was 57 years. The youngest patient was 40 years old and the oldest patient was 71 years old.

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 four countries.



What were the main results of the study?

The main focus of the study was to compare blood eosinophil levels and lung inflammation between the treatment groups.

Patients with moderate to severe asthma with AFAD have increased numbers of eosinophils. Too many eosinophils may worsen asthma symptoms by increasing lung inflammation. Lung inflammation increases the levels of a gas (nitric oxide) in a patient's breath. A test was done to measure the levels of this gas.

On average, patients in both the treatment groups showed some reduction in blood eosinophil levels and lung inflammation at Week 12 compared with Day 1 (the first day of the treatment period).

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).

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

In this summary, side effects refer to those events that the study doctor thinks may have been caused by the study medicine. The side effects in this summary may be different to those in the Informed Consent or other documents related to the study medicine.

In this study, side effects were collected from the first day of the treatment period to 12 weeks after the end of the treatment period.

- No serious side effects were reported.
- No non-serious side effects were reported by any patients in the GSK3772847 group. One patient in the placebo group had three non-serious side effects.

How has this study helped patients and researchers?

Researchers could not draw any conclusions due to the small number of patients in the study.

Are there plans for further studies?

No studies of GSK3772847 in patients with moderate to severe asthma with AFAD are currently planned or 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 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)	2017-003544-20[1]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03393806[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 moderate to severe asthma with AFAD.

The content for this document was finalised by GSK on the 4th of December 2020. The information in this summary does not include additional information available after this date.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=2017-003544-20

[2] https://clinicaltrials.gov/ct2/show/NCT03393806?term=207972&draw=2&rank=1