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 long-term safety of mepolizumab in patients with hypereosinophilic syndrome.

Full Scientific Title: A multi-centre, open-label extension, safety study to describe the long-term clinical experience of mepolizumab in participants with hypereosinophilic syndrome (HES) from Study 200622.

Study Number: 205203

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 November 2017 and ended in December 2019.

What was the main objective of this study?

High levels of a type of white blood cell (eosinophils) can lead to a condition called hypereosinophilic syndrome (HES). Eosinophils help the body fight infections. Too many eosinophils may cause inflammation that can damage the body's internal organs.

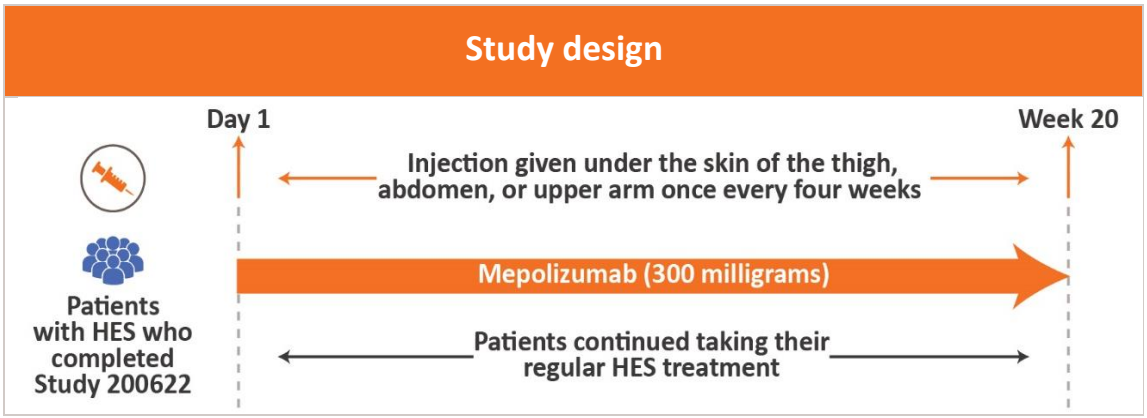
Mepolizumab is a medicine that lowers the number of eosinophils in the blood.

The main objective of this study was to assess the long-term safety of mepolizumab in patients with HES. Safety was measured by recording the number of unwanted medical

events (adverse events) and the number of patients who made proteins that bind to mepolizumab (anti-mepolizumab antibodies).

Which medicine was studied?

Patients knew that they were receiving mepolizumab (see figure below). This is called an open-label study.



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.

Males and females with HES who completed Study 200622 were included in this study.

Males and females were excluded from the study if they had:

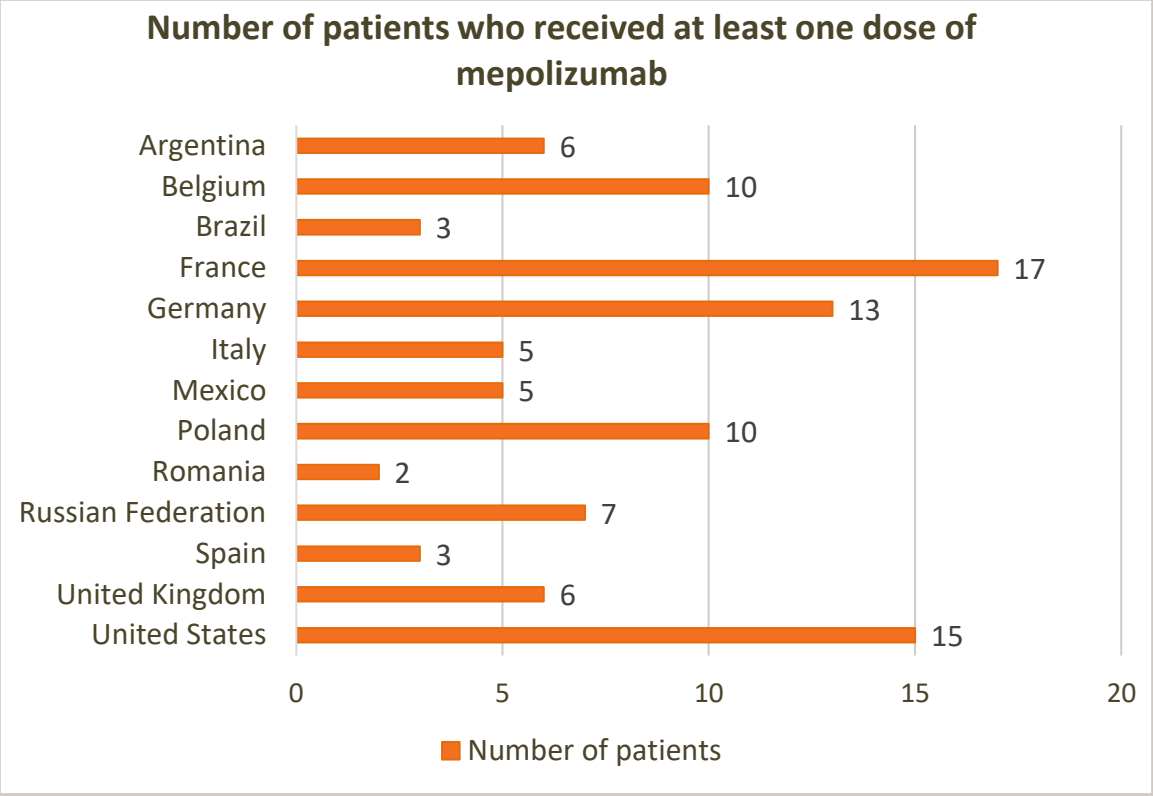
- An adverse event that the study doctor thought was caused by the study medicine (side effect) and the study medicine was withdrawn during Study 200622.
- Cancer or liver disease during or after participating in Study 200622.
- Any other disease(s) that the study doctor thought would affect the results of the study.

Overall, 102 patients received at least one dose of mepolizumab in this study. The study included 47 (46%) males and 55 (54%) females. The average age was 46 years. The youngest patient was 13 years old and the oldest patient was 81 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 13 countries.



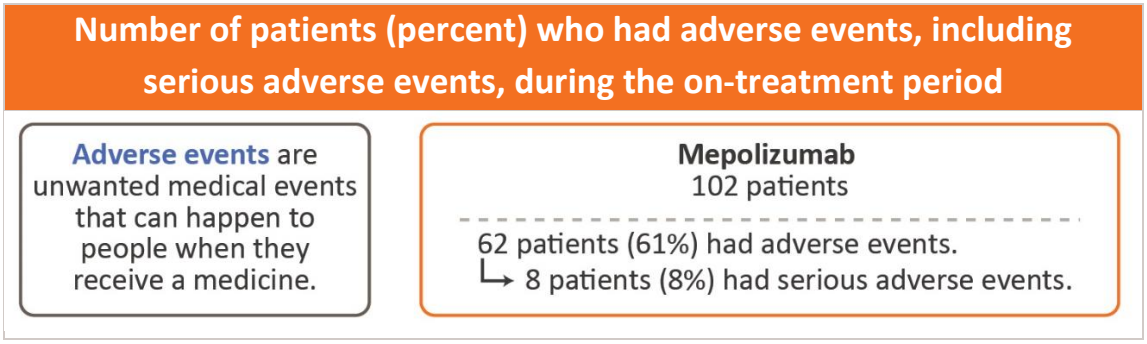
What were the main results of the study?

Safety was measured by:

- Recording the number of patients who had adverse events.
- Checking the patients' blood samples for the presence of anti-mepolizumab antibodies.

Adverse events

The figure below shows the number of patients (percent) who had adverse events, including those who had serious adverse events, during the on-treatment period (from Day 1 to four weeks after they received the last dose of mepolizumab).



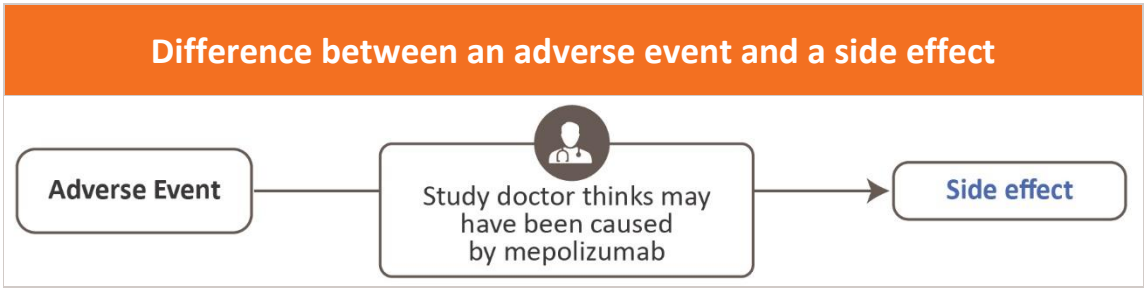
Anti-mepolizumab antibodies

Long-term treatment with mepolizumab may cause the patient's body to make anti-mepolizumab antibodies. Study doctors checked the patients' blood samples on Day 1, Week 20, and Week 28. Anti-mepolizumab antibodies were found in the blood sample of one patient (out of 102 patients) on Day 1. No patients had anti-mepolizumab antibodies after Day 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?

In this summary, side effects refer to those adverse events that the study doctor thinks may have been caused by mepolizumab, as shown in the figure below.



The side effects in this section may be different to those in the Informed Consent or other documents related to mepolizumab.

During the study, one patient (less than 1%) had a serious side effect of inflammation in the sinuses.

The table below shows the number of patients (percent) with non-serious side effects reported by 3% or more of patients during the study.

Number of patients (percent) with non-serious side effects reported by 3% or more of patients	
	Mepolizumab 102 patients
Injection site reaction	4 (4%)
Headache	3 (3%)

How has this study helped patients and researchers?

The main objective of this study was to assess the long-term safety of mepolizumab in patients with HES who completed Study 200622. Eight patients had serious adverse events during the on-treatment period. No patients had anti-mepolizumab antibodies after Day 1.

Are there plans for further studies?

Other studies of mepolizumab in patients with HES have been conducted. No new 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)	2017-000184-32[1]
United States National Institutes of Health (NIH) (www.clinicaltrials.gov)	NCT03306043[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 HES.

The content for this document was finalised by GSK on the 24th of September 2020. The information in this summary does not include additional information available after this date.

[1] https://www.clinicaltrialsregister.eu/ctr-search/search?query=205203
[2] https://clinicaltrials.gov/ct2/show/NCT03306043