This document provides a short summary of this study for a general audience. You can find more information in scientific summaries of the study. Links to those summaries are provided at the end of this document.

Study Identification

Short Title**:** A study of fluticasone furoate and vilanterol on arterial stiffness in patients with Chronic Obstructive Pulmonary Disease (COPD).

Full Scientific Title**:** A 24-week study to evaluate the effect of fluticasone furoate/vilanterol 100/25 mcg inhalation powder delivered once-daily via a Novel Dry Powder Inhaler on arterial stiffness compared with placebo and vilanterol in subjects with Chronic Obstructive Pulmonary Disease (COPD).

Name and Contact Details of the Sponsor

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

General Information about the Clinical Study

Study Dates: The study started in March 2011 and ended in November 2014.

The Reason for Conducting This Study

People with Chronic Obstructive Pulmonary Disease (COPD) are more likely to develop heart problems compared with healthy people. Arterial stiffness, also known as hardening of the arteries, increases the risk of heart disease. This study looked at whether or not medicines for COPD improved arterial stiffness, which may lead to a lower risk of heart disease. In this Phase IIIB study, researchers compared the effects of two medicines used to treat COPD (a combination treatment), a single medicine, and no medicine (placebo).

The study also assessed the adverse reactions that patients experienced when given these medicines.

Participants

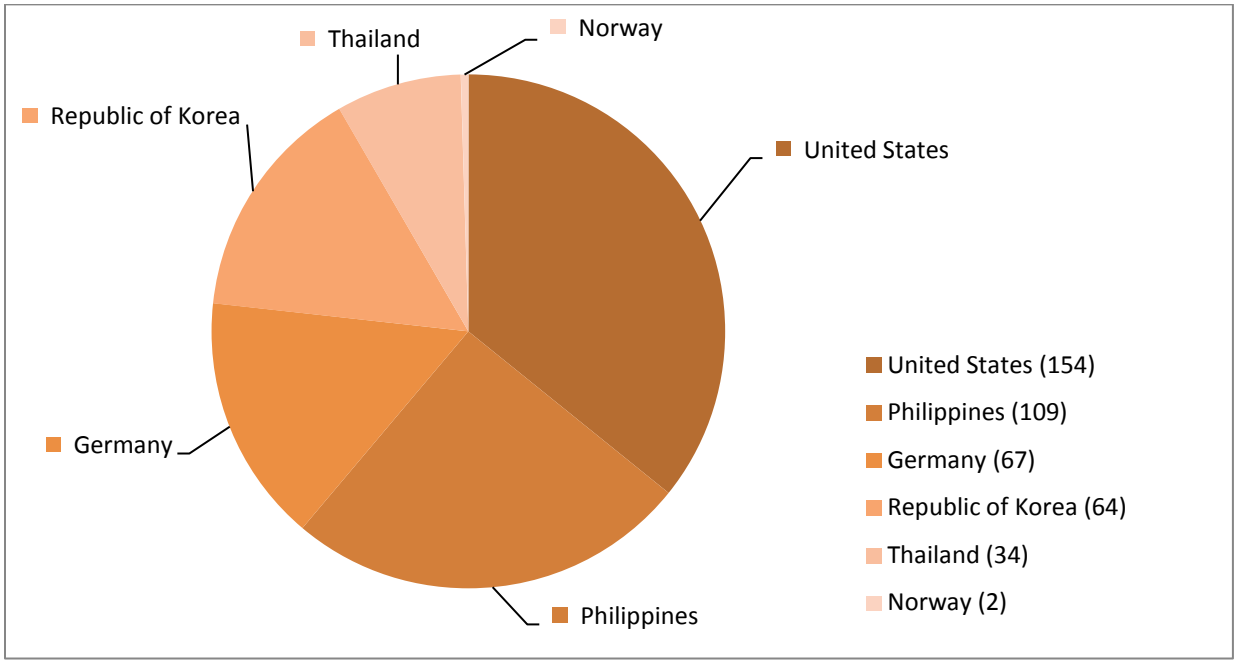
Patients Included

The study was open to patients with COPD who were 40 years old or older and had smoked a lot in the past.

The study included 430 patients. The youngest patient was 41 years old and the oldest was 87. The average age was 68.5 years. More of the patients (79%) were men.

Study Site Locations

Study sites were located in 6 countries. The graph below shows how many patients were from each country.



Investigational Medicinal Products Used

Medicines used

The study compared three inhaled medicines.

1. A medicine that reduces inflammation (fluticasone furoate) in combination with a medicine that opens the airways (vilanterol).
2. A medicine that opens the airways (vilanterol).
3. A placebo (an inactive medicine).

Results of the Clinical Study

Results

This study found no difference in arterial stiffness between patients treated with fluticasone furoate and vilanterol, vilanterol alone, and placebo as shown in the table below.

Table 1. Main Results of the Study

Measure of Arterial Stiffness: Average Pulse Wave Velocity in meters per second (m/sec)	**Fluticasone Furoate and Vilanterol**	**Vilanterol**	**Placebo**
Baseline			
Number of patients	131 patients*	153 patients*	141 patients*
Average m/sec	13.2 m/sec	13.3 m/sec	13.2 m/sec
Day 168			
Number of patients	103 patients*	117 patients*	85 patients*
Adjusted average m/sec	11.5 m/sec	11.3 m/sec	11.3 m/sec
Change from Baseline			
Change in adjusted average m/sec from Baseline to Day 168	-1.7 m/sec	-2.0 m/sec	-2.0 m/sec

*Results are from the patients who completed the necessary tests.

Description of Adverse Reactions and Their Frequency

Adverse Reactions

Researchers collect information about the safety of study medicines.

- An ***adverse reaction*** means a medical problem that develops during the study that the doctor thinks could have been caused by the patient's study medicine.

- A ***serious adverse reaction*** means an adverse reaction that is life threatening, requires hospitalization, or results in death or permanent damage.

For blinded studies, the study doctor does not know if the patient is receiving placebo or an active medicine. In some cases, adverse reactions will be assigned to placebo.

Table 2 shows the serious adverse reactions reported by one or more patients.

Table 2. Serious Adverse Reactions

	Fluticasone Furoate and Vilanterol 141 patients*	Vilanterol 158 patients*	Placebo 145 patients*
Severe COPD Symptoms (Exacerbation)	1 of 141 (Less than 1%)	0 of 158 (0%)	1 of 145 (Less than 1%)
Pneumonia	0 of 141 (0%)	0 of 158 (0%)	1 of 145 (Less than 1%)

*The safety population included additional patients who took at least one dose of the study medicine.

Table 3 shows the non-serious adverse reactions that were reported by 3% or more of patients who received treatment.

Table 3. Non Serious Adverse Reactions			
	Fluticasone Furoate and Vilanterol 141 patients*	Vilanterol 158 patients*	Placebo 145 patients*
Yeast Infection in the Mouth (Oral Candidiasis)	6 of 141 patients (4%)	2 of 158 patients (1%)	1 of 145 patients (Less than 1%)

*The safety population included additional patients who took at least one dose of the study medicine.

Comments on the Outcome of the Clinical Study

What did this study tell researchers?

The study found that fluticasone furoate and vilanterol did not improve arterial stiffness in patients with COPD.

This summary shows the results from one study. Other studies may find different results.

We would like to thank the patients who contributed. The results of this study will help answer important scientific questions.

Further Studies

Other studies of fluticasone furoate and vilanterol in patients with COPD are currently planned and others are ongoing. The results of these studies will also be available on GlaxoSmithKline's Clinical Study Register after the studies end and the results are analyzed (See link below).

No additional studies are currently planned for arterial stiffness in COPD patients with fluticasone furoate and vilanterol.

Where Additional Information Can Be Found

Clinical studies have unique study numbers which are included in publications and other information about the study. Below are the unique study numbers associated with this study. The hyperlink text connects to scientific summaries and other information on the Internet.*

Organization	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2010-023091-10
US National Institutes of Heath (NIH)	www.clinicaltrials.gov	NCT01336608
GlaxoSmithKline (GSK)	www.gsk.clinicalstudyregister.com	HZC113108

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

This document was developed and approved by GSK on 9 December 2016. The information in this summary does not include additional information available after this date.

* If you are reading this document in hard copy and cannot access the websites through the hyperlinks embedded in this document, you can type the following web addresses in your browsers.
EudraCT summary: https://www.clinicaltrialsregister.eu/ctr-search/search?query=2010-023091-10
US NIH/clinicaltrials.gov: https://clinicaltrials.gov/ct2/results?term=113108&Search=Search
GSK Clinical Study Register: http://www.gsk-clinicalstudyregister.com/search/?study_ids=113108#