Who Sponsored this study?
GlaxoSmithKline

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Can a Vaccine Prevent Exacerbation of COPD Symptoms?

GSK would like to thank all the people who took part in this clinical study. We think it is important that you know the study results. We hope it helps you understand and feel proud about your important role in medical research.

Overview

Why was this study done?

The main goal of the study was to find out how effective a vaccine in development for chronic obstructive pulmonary disease (COPD) is in reducing the number of COPD exacerbations. Exacerbation was defined by the study doctor. The doctor's decision was based on symptoms reported by the patient, increased use of COPD medications or a COPD related hospitalisation.

What was studied?

- The number of times patients suffered moderate to severe exacerbation of their COPD symptoms.
- Possible vaccine side effects.

Who was in this study?

- 606 patients with moderate, severe or very severe COPD (245 women and 361 men) from 8 countries participated in this study. They were 40 to 80 years old when they got their first study injection.

What kind of study was it?

- This was an observer-blind study. Neither the study doctor nor the patient knew if a vaccine or placebo was given.
- This was a placebo-controlled study. Half the patients who participated received the study vaccine. The other half received injections of an inactive placebo.

Main results

- The number of COPD exacerbations was similar in both study groups, even though the vaccine brought about a strong immune response.
- In all, this study revealed no new safety concerns about the study vaccine. There were more serious breathing-related side effects in patients who received the inactive placebo injection than the study vaccine.

NCT number: NCT03281876

EudraCT number: 2017-000880-34

General information about the research study

When was the study done?

The study started in November 2017 and ended in March 2020.

Why was this study done?

COPD is a disease of the lungs, usually linked to smoking and breathing polluted air. Two bacteria, called *Haemophilus influenzae* and *Moraxella catarrhalis* are commonly found in the lungs of COPD patients and can cause exacerbation.

The study vaccine may help protect against these 2 bacteria. The vaccine contains parts of the bacteria that cannot cause infection. They help the body make defences, known as antibodies, against those bacteria. The vaccine also contained an ingredient known as an adjuvant. The adjuvant is added to increase and prolong the body's response to the vaccine.

The main goal of the study was to learn about the effectiveness of 2 doses of the vaccine. The researchers' aim was to reduce the number of moderate to severe COPD exacerbations.

Exacerbation was defined by the study doctor. The doctor's decision was based on symptoms reported by the patient, increased use of COPD medications or a COPD related hospitalisation.

Who took part in this study?

606 COPD patients from 8 countries

40 to 80 years old when they got the first vaccination/injection

245 women (40%)

361 men (60%)

COPD patients could take part in the study if they:

- had a confirmed diagnosis of moderate, severe or very severe COPD
- were current or former smokers with a smoking history of 10 or more pack-years
- were stable patients with a history of at least 1 exacerbation within the 12 months prior to the study

COPD patients could not take part in the study if they:

- took certain medicines that might alter the immune system response to the vaccine
- took another investigational or non-registered vaccine or drug shortly before they started the study
- had a planned lung transplantation or resection
- had certain types of COPD or a different respiratory or immune disorder
- had an unstable or life-threatening cardiac disease
- were pregnant or breastfeeding

Which vaccines were studied?

- The study vaccine was being developed to protect against diseases caused by 2 bacteria, *Haemophilus influenzae* and *Moraxella catarrhalis*.
- Placebo: a buffered saltwater solution.

How was the study done?

The study was done as described below in Figure 1. COPD patients were placed in 1 of 2 study groups:

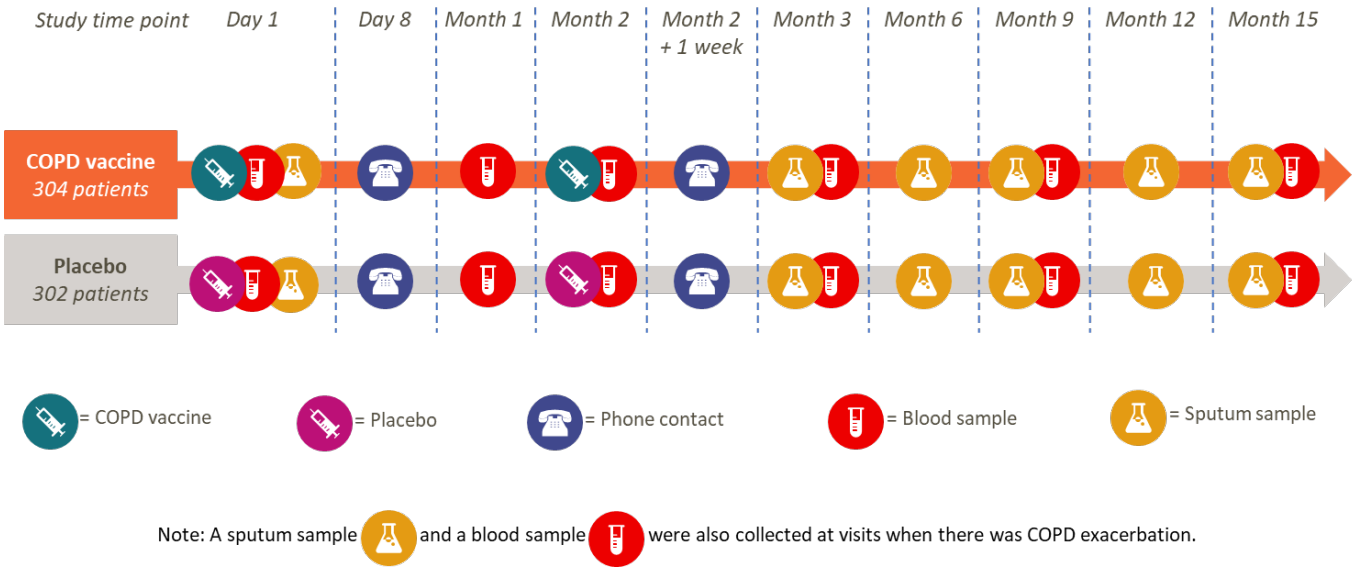
COPD vaccine group: These patients got 2 injections of COPD vaccine; one on the first day and another 2 months after.

Placebo group: in this group, COPD patients got 2 injections of placebo; one on the first day and another 2 months after.

Blood and sputum samples were taken to assess the body's defence response to the vaccine. However, this was not the main goal of this study. Complete results can be found in the clinical results summary.

Information on potential side effects was collected from study participants via telephone.

Figure 1. Study design



What were the main results of the study?

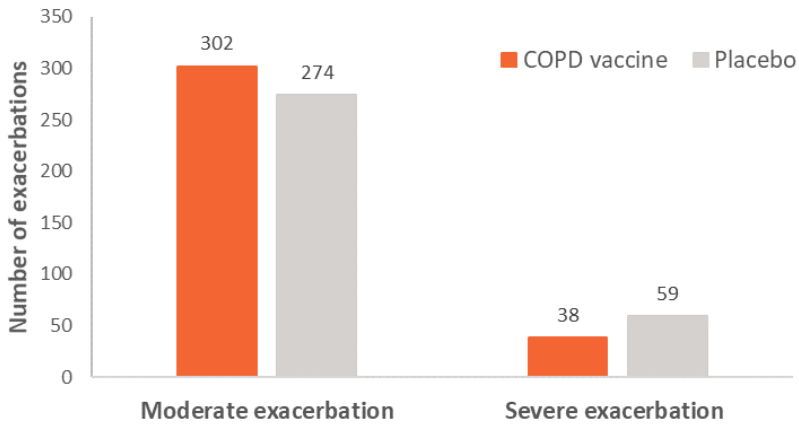
This report provides the results of the main results from the study. All results may be found in the clinical results summary.

Effectiveness of the COPD vaccine

The main goal of the study was to measure the ability of 2 doses of a COPD vaccine to lower the number of times patients had moderate to severe exacerbation of their COPD symptoms.

COPD exacerbation measurement started 1 month after the second vaccine dose and continued for 12 months. In that time, COPD exacerbations were similar in both groups. (Figure 2).

Figure 2. Exacerbation of COPD



What were the side effects?

Unwanted medical events (adverse events) can happen to people when they receive a vaccine. Study doctors record these events. A summary of all events reported in this study may be found in the *clinical results summary.*

If the study doctor thinks that the event was caused by the vaccine, they record this as a possible side effect (adverse reaction).

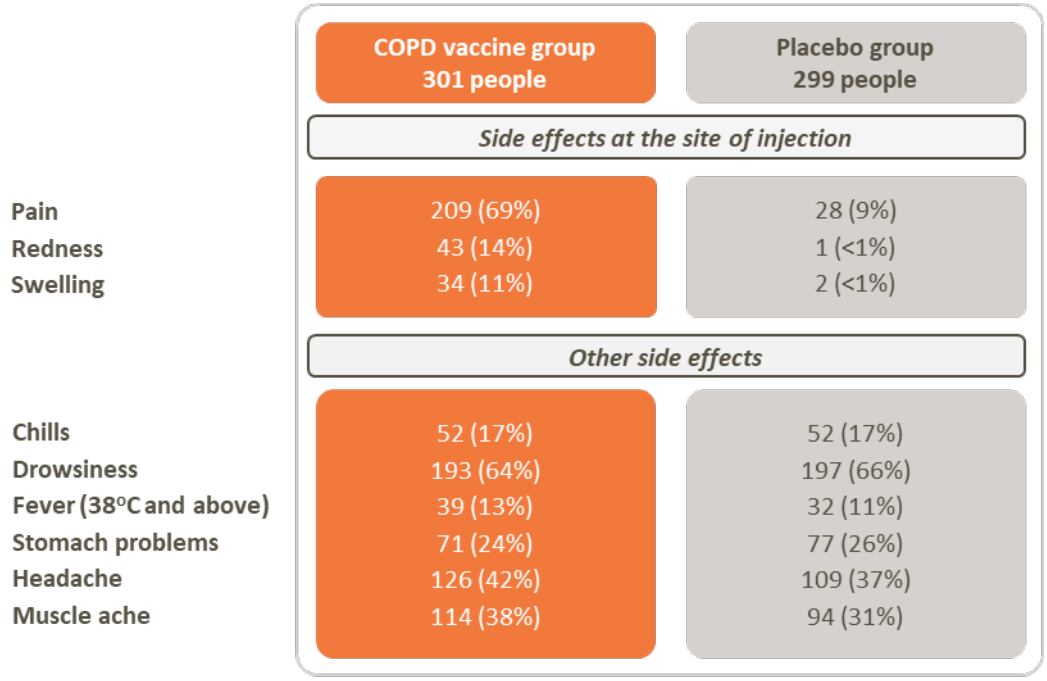
In this summary, "side effects[1]" refer to those events that the study doctor thinks may have been caused by the study vaccine.

In this study, there were 600 patients who reported at least one side effect at the injection site or one other side effect between day 1 and day 7 after each vaccination. (Figure 3, below).

This study revealed no new safety concerns about the study vaccine.

[1] *The use of the term side effects in this summary may be different to that in the Informed Consent or other documents related to the vaccine.*

Figure 3. Side effects within 7 days after vaccine or placebo was given*



Some volunteers had more than one side effect

How has this study helped patients and researchers?

This study helped researchers in 3 ways. It showed that the vaccine was not able to reduce COPD exacerbations. It showed that the vaccine could stimulate a strong antibody response in those who received it. It also confirmed that the rate of bacterial (*Haemophilus influenzae* and *Moraxella catarrhalis*) infection in this group of patients was what the researchers had assumed it would be.

A summary of all the ways this study helped patients and researchers may be found in the *clinical results summary.*

Are there plans for further studies?

No other studies were planned or ongoing to evaluate the effectiveness of the study vaccine at the time this summary was prepared. The results of any future studies will be available on the websites of European Medicines Agency and/or the United States National Institutes of Health. Links to this study are provided at the end of the document.

Where can I find more information about this study?

The detailed title for this research study is:

A Phase IIB, randomised, observer-blind, placebo-controlled, multi-centre study to evaluate the efficacy, safety, reactogenicity and immunogenicity of the GSK Biologicals' investigational vaccine GSK3277511A when administered intramuscularly according to a 0, 2 month schedule in COPD patients aged 40 to 80 years with a previous history of acute exacerbation (AECOPD).

Clinical studies have unique study numbers. Below are the unique study numbers associated with this study.

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Organisation	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2017-000880-34
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03281876

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.

This document was developed and approved by GSK on 16 October, 2020. The information in this summary does not include additional information available after this date.

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 below.

For readers of this document in text form, the websites associated with the hyperlinks above are:

EudraCT summary:
https://www.clinicaltrialsregister.eu/ctr-search/trial/2017-000880-34/EN
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT03281876