Who sponsored this study?
GlaxoSmithKline

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A study of the safety and immune response of NTHi Mcat vaccine in adults after they got shingles vaccine

GSK would like to thank all those 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.

General information about the research study

When was the study done?

The study started in April 2019 and ended in August 2021.

Why was this study done?

Sometimes, additional components are added to vaccines to make them work better. These components are called 'adjuvants'. This study was done to find out the best time window to give 2 vaccines containing the same adjuvant.

Non Typeable *Haemophilus influenzae* and *Moraxella catarrhalis* (NTHi and Mcat) are bacteria that can cause worsening of a chronic lung disease known as chronic obstructive pulmonary disease (COPD). In COPD, airflow to lungs is obstructed, making it difficult to breathe. Vaccines may help protect against infection by NTHi and Mcat. They contain parts of the bacteria that cannot cause infection. These parts help the body make defenses, known as antibodies, against those bacteria.

The main goal of the study was to compare antibodies between adults who either got NTHi Mcat vaccine after receiving shingles vaccine or NTHi Mcat vaccine alone.

To be sure that vaccination with NTHi Mcat vaccine is beneficial, it is important to understand the side effects this vaccine may have.

Study doctors collected information about potential side effects to the vaccines given in this study. The results can be found in the section "What were the side effects?".

This report focuses on the results of the main goals of the study. All results may be found in the ***clinical results summary.***

Who took part in this study?

541 adults from **Estonia, Finland, France, Italy and Spain**

50 to 80 years old when they got their first vaccination

259 women (48%)

282 men (52%)

Adults could take part in the study if they:

- were former or current smokers with a history of cigarette smoking as defined for this study
- did not have autoimmune diseases, COPD, alcoholism and/or drug abuse

Adults could not take part in the study if they:

- previously received any shingles vaccine(s) or vaccine(s) containing NTHi and/or Mcat
- previously received any vaccine containing the adjuvant used in this study
- were pregnant or planning to become pregnant when they started the study

Which vaccines were studied?

NTHi Mcat vaccine: a vaccine that has been developed to protect against 2 different bacteria known as NTHi and Mcat. This vaccine was given by injection into the arm.

Shingles vaccine: a vaccine that has been developed to protect against shingles. This vaccine was given by injection into the arm.

How was the study done?

Figure 1 describes which vaccines adults in each study group got and when they got them. It also shows when blood samples were taken. These samples were taken to measure antibodies. Study doctors also collected information on the safety of the vaccine.

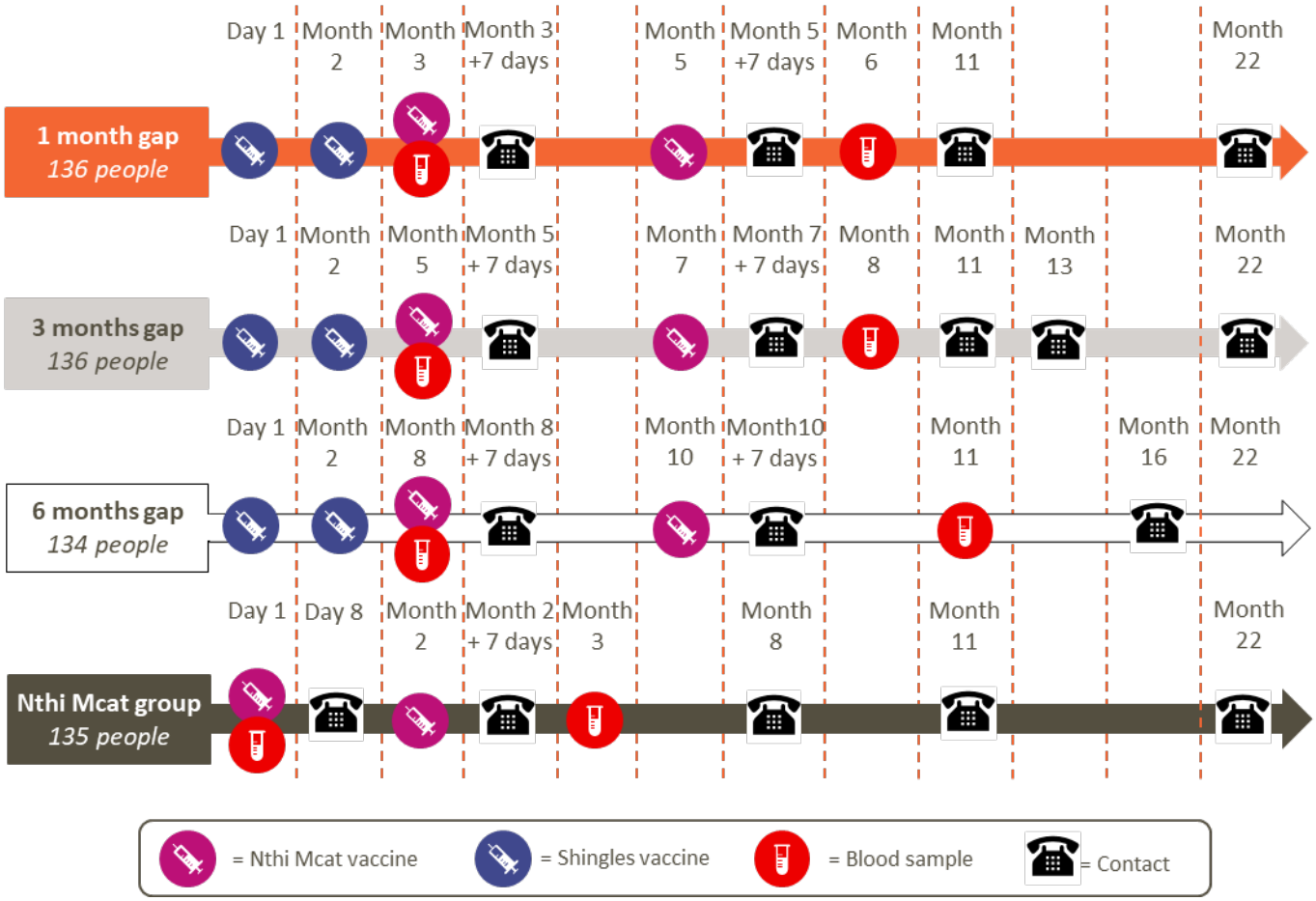
The study took approximately 2 years for all adults.

The adults were assigned to a study group by chance (like tossing a coin). Adults were assigned to one of the 4 groups which differed by the gap between the shingles vaccine and NTHi Mcat vaccine:

- One group received the NTHi Mcat vaccine after a gap of 1 month
- One group received the NTHi Mcat vaccine after a gap of 3 months, and
- One group received the NTHi Mcat vaccine after a gap of 6 months
- One group received only the NTHi Mcat vaccine

Both the study staff and the adults knew which treatment the adults got.

Figure 1: Study design



What were the main results of the study?

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

Immune responses to NTHi Mcat vaccine and shingles vaccine

There were no important differences between the antibody levels in adults who got the NTHi Mcat vaccine 1 month after shingles vaccine and those who got NTHi Mcat vaccine alone. Adults who got the NTHi Mcat vaccine 3 months and 6 months after they got the shingles vaccine had similar levels of antibodies as compared to adults who got NTHi Mcat vaccine alone.

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*" refer to those events that the study doctor thinks may have been caused by the study vaccine.

Pain was the most frequently reported side effect at the place of injection (arm) after vaccination (Figure 2).

Tiredness was the most frequently reported side effect after vaccination (Figure 2).

Two participants in the NTHi Mcat group reported skin itching within 1 month after vaccination.

No study participants withdrew from the study because of a vaccine side effect. Fewer than 1% participants reported a serious side effect: 1 participant in the 1-month gap group, reported 2 serious side effects. These were polymyalgia rheumatica (a condition that results in muscle pain and stiffness in different parts of the body), and giant cell arteritis (swelling up of blood vessels in the head). Both side effects were resolved by the end of the study with some long-term effects.

This study did not raise any safety concerns about the NTHi Mcat vaccine.

**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 2: Side effects reported by at least 2 participants

	1 month gap 134 people	3 months gap 133 people	6 months gap 120 people	Nthi Mcat group 135 people
	Side effects at the site of injection			
Pain	105 (78%)	112 (84%)	98 (82%)	112 (83%)
Redness	21 (16%)	27 (20%)	28 (23%)	24 (18%)
Swelling	12 (9%)	19 (14%)	13 (11%)	15 (11%)
	Other side effects			
Tiredness	63 (47%)	78 (59%)	69 (58%)	65 (48%)
Headache	55 (41%)	64 (48%)	43 (36%)	41 (30%)
Muscle pain	48 (36%)	64 (48%)	56 (47%)	66 (49%)
Chills	40 (30%)	41 (31%)	39 (33%)	26 (19%)
Stomach conditions	34 (25%)	32 (24%)	26 (22%)	26 (19%)
Fever	16 (12%)	12 (9%)	13 (11%)	14 (10%)

**Some volunteers had more than one side effect*

How has this study helped patients and researchers?

The results from this study show that it is safe to give NTHi Mcat vaccine to adults 1, 3 or 6 months after they got a shingles vaccine containing the same adjuvant. Moreover, the results showed that there is no difference in the immune response to the NTHi Mcat vaccine if it is given alone or if it is given after the shingles vaccine.

This summary only shows results from one study. Other studies may find different results. Combined with results from other research studies, the findings from this study may help improve the understanding of NTHi Mcat vaccine.

Are there plans for further studies?

At the time of preparation of this summary, no other studies to evaluate the NTHi Mcat vaccine were ongoing or planned. New studies with NTHi Mcat vaccine may be planned in the future.

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 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 IIA, open-label study to evaluate the immunogenicity and safety of sequential use of GSK's investigational vaccine GSK3277511A when administered to healthy smokers and ex-smokers aged 50 to 80 years following receipt of *Shingrix* vaccine.

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

Organization	Website	Study Number
European Medicines Agency	www.clinicaltrialsregister.eu	2018-002977-24
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03894969

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.

Version 1 of this document was developed and approved by GSK on 21 January 2022. This summary does not include additional information available after this date.

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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/2018-002977-24/results
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/NCT03894969?term=2018-002977-24&draw=2&rank=1