Who sponsored this study?
GlaxoSmithKline

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A study of the safety of NTHi Mcat vaccine in adults

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.

Overview

Why was this study done?

The main goal of the study was to see if a third dose of the NTHi Mcat vaccine is safe if it is given 6 or 12 months after the second dose.

What was studied?

- Safety of NTHi Mcat vaccine.

Who was in this study?

89 women and 111 men from the United Kingdom, Germany, and Canada took part in the study. They were 40 to 80 years old when they got their first vaccination.

What kind of study was it?

- Randomized: Adults who joined this study were assigned to a study group by chance (like tossing a coin).
- Observer-blind: neither the study staff nor study participants knew which treatment was given.

Main results

- This study did not raise any safety concerns about NTHi Mcat vaccine.
- No study participant withdrew from the study because of a vaccine side effect. Approximately 10% of study participants reported a serious medical event. None of them were considered to be caused by the study vaccine.

NCT number: NCT03443427
EudraCT number: 2017-002941-31

General information about the research study

When was the study done?

The study started in March 2018 and ended in September 2020.

Why was this study done?

Sometimes, an additional vaccine dose may improve the immune response. We first need to find out if it is safe to give that additional dose to people, and what is the best time to give it. The main goal of the study was to see if a third dose of the NTHi Mcat vaccine is safe if it given 6 or 12 months after the second dose.

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 vaccine given in this study according to 2 schedules:

- vaccination at 0, 2, 6 months;
- vaccination at 0,2, 12 months.

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

Non Typeable *Haemophilus influenzae* and *Moraxella catarrhalis* (NTHi and Mcat) are bacteria that can cause the worsening of a chronic lung disease known as chronic obstructive pulmonary disease (COPD), where the airflow to lungs is obstructed, making it difficult to breathe. Vaccines can 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.

Who took part in this study?

200 adults from the **United Kingdom**, **Germany**, and **Canada**.

40 to **80 years** old when they got their first vaccination.

89 women (**45%**)

111 men (**55%**)

Adults could take part in the study if they:

- were former or current smokers with a smoking history of 10 or more pack-years
- did not have respiratory disorders, autoimmune diseases, alcoholism and/or drug abuse

Adults could not take part in the study if they:

- previously received vaccines containing NTHi and/or Mcat
- were pregnant or planning to become pregnant or were breastfeeding when they started the study

Which vaccines were studied?

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

Placebo: an inactive solution. The placebo was given by injection into the arm.

How was the study done?

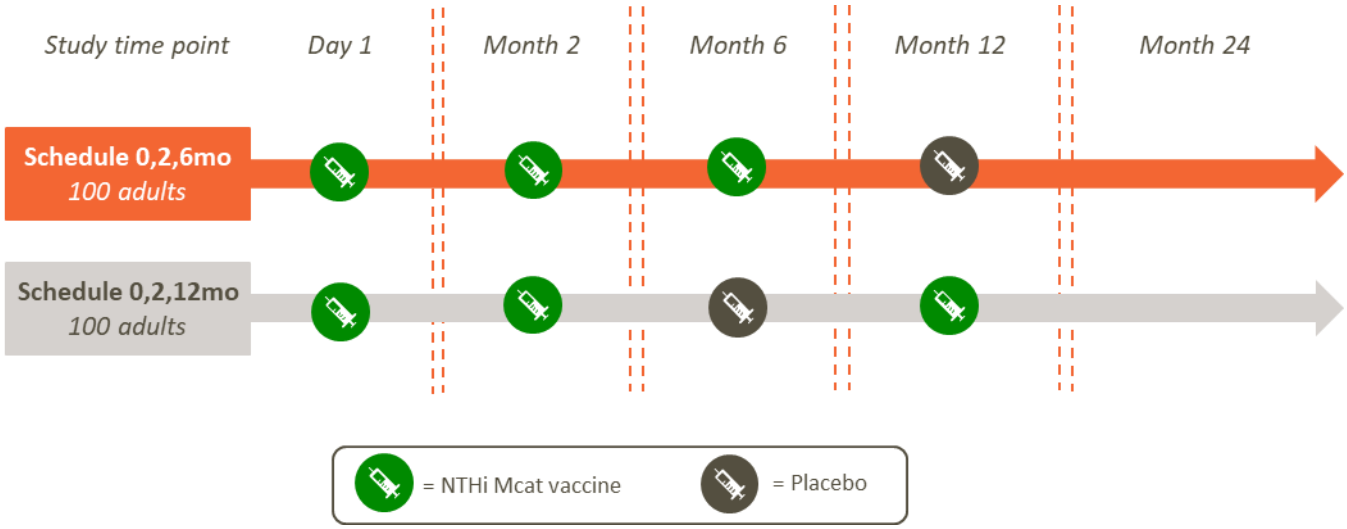
Figure 1 describes which vaccines adults in each study group got and when they got them. Study doctors collected information on the safety of the vaccine.

The study took approximately 2.5 years for all adults.

Adults who joined this study were assigned to a study group by chance (like tossing a coin).

Neither the study staff nor study participants knew which treatment was given.

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**.*

Safety of NTHI-MCAT vaccine

The main goal of the study was to assess the safety of the NTHi Mcat vaccine.

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 NTHi Mcat vaccination (**Figure 2**).

**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.*

Fatigue was the most frequently reported other side effect after NTHi Mcat vaccination (**Figure 2**).

This study did not raise any new safety concerns about NTHi Mcat vaccine. Approximately 10% of study participants reported a serious medical event. None of them were considered to be caused by the study vaccines. No study participant withdrew from the study because of a vaccine side effect.

The body's defenses (immune response) were also tested in the study. This was not a main goal of the study, and those results can be found in the ***clinical results summary.***

Figure 2: Side effects in at least 2 participants

	Schedule 0,2,6mo 100 adults	Schedule 0,2,12mo 100 adults
Side effects at the site of injection		
Pain	89 (89%)	92 (92%)
Redness	21 (21%)	28 (28%)
Swelling	16 (16%)	20 (20%)
Other side effects		
Fatigue	44 (44%)	50 (50%)
Headache	39 (39%)	41 (41%)
Muscle pain	38 (38%)	40 (40%)
Stomach disorders	25 (25%)	27 (27%)
Chills	24 (24%)	24 (24%)
Fever (38°C and above)	11 (11%)	13 (13%)

**Some volunteers had more than one side effect*

How has this study helped patients and researchers?

The results from this study indicate that the NTHi Mcat vaccine was safe when given to adults in the different dose schedules tested in the study.

Combined with results from other research studies, the findings from this study may help improve the understanding of NTHi Mcat vaccine and COPD.

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Are there plans for further studies?

This study was part of a program to see if a candidate vaccine could prevent worsening of COPD. At the time of preparation of this summary, one other study was ongoing to evaluate the NTHi Mcat vaccine. New studies with this 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

**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.*

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 2, randomised, observer-blind, multi-centre study to evaluate the safety, reactogenicity and immunogenicity of GSK Biologicals' GSK3277511A investigational vaccine when administered intramuscularly according to two different vaccine schedules in adults aged 40 to 80 years old.

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	2017-002941-31
United States National Institutes of Health (NIH)	www.clinicaltrials.gov	NCT03443427

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 April 2021. 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/2017-002941-31/results
US NIH/clinicaltrials.gov:
https://clinicaltrials.gov/ct2/show/results/NCT03443427?view=results