Clinical Study Results

This summary reports the results of only one study. Researchers must look at the results of many types of studies to understand if a study vaccine works, how it works, and if it is safe to prescribe to study participants. The results of this study might be different than the results of other studies that the researchers review.

Sponsor: Pfizer, Inc.

Vaccine(s) Studied: Group B Streptococcus 6-Valent Polysaccharide Conjugate Vaccine (GBS6)

Protocol Number: C1091007

Dates of Study: 11 February 2020 to 15 September 2020

Title of this Study: A Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a Booster Dose of a Group B Streptococcus 6-Valent Polysaccharide Conjugate Vaccine in Health Adults

[A Phase 2, Open-Label Trial to Evaluate the Safety, Tolerability, and Immunogenicity of a Booster Dose of a Group B Streptococcus 6-Valent Polysaccharide Conjugate Vaccine (GBS6) in Healthy Adults]

Date(s) of this Report: 15 November 2021

– Thank You –

If you participated in this study, Pfizer, the Sponsor, would like to thank you for your participation.

This summary will describe the study results. If you have any questions about the study or the results, please contact the doctor or staff at your study site.

Why was this study done?

What is Group B Streptococcus?

Group B Streptococcus (GBS) is a germ (bacteria) that may cause serious disease, including sepsis (a systemic inflammatory reaction that may affect several organs in the body), meningitis (infections of the lining covering the brain and spinal cord), and pneumonia (lung infection).

What is GBS6?

Group B streptococcus 6-valent polysaccharide conjugate vaccine (GBS6) is a vaccine under development to prevent disease caused by 6 different types of GBS infection. Vaccines help a person's body with the ability to prevent infection from GBS using the body's disease-fighting system (immune response). GBS6 is made from a weakened part of the germ (sugar coat of bacteria) added to a separate stronger carrier protein which helps increase the body's immune response after vaccination.

What was the purpose of this study?

This study is a follow-up to a previous study where participants received 1 of 6 dose/formulations of GBS6 or a placebo, approximately 2 years before this study. The purpose of the study was to evaluate the safety and tolerability of a booster dose of GBS6, an investigational vaccine, in healthy adults. Investigational means that a vaccine is not approved for use in this country. Safety means that any reactions or medical problems that happened in the study were studied. Tolerability refers to whether reactions to the vaccine interfered with a participant's usual activities.

What happened during the study?

Researchers tested 2 forms of GBS6 in 2 groups of study participants to find out if GBS6 was safe and well-tolerated. The 2 forms of vaccine were GBS6 with aluminium phosphate ($AlPO_4$) and GBS6 without $AlPO_4$.

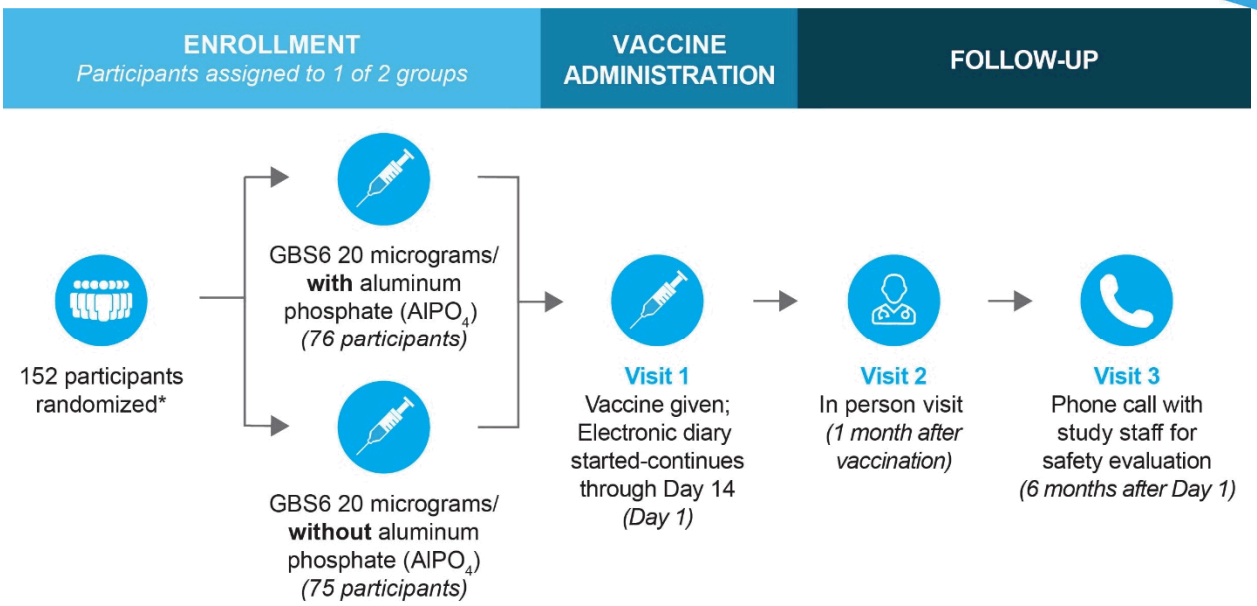
- The study was an open-label study which mean that participants and researchers knew which vaccine they were receiving. Participants received the same form of vaccine (GBS6 with $AlPO_4$ or GBS6 without $AlPO_4$) as they received in the previous study. The dose of vaccine given in this study is considered to be a booster dose.

- Participants received a shot of their assigned vaccine in their upper arm on Day 1 of the study.

- Participants recorded any reactions or other medical problems in an electronic diary for 14 days following study vaccination.

- 1 month after receiving the vaccine, participants had a clinic visit to have their blood drawn, see how they were doing, and report any medical problems.

- 6 months after receiving the vaccine, participants received a phone call to see how they were doing and to report any medical problems.



** 1 participant did not receive vaccine*

Where did this study take place?

The Sponsor ran this study at 4 locations in the United States.

When did this study take place?

It began February 2020 and ended September 2020.

Who participated in this study?

The study included participants who were healthy adults and received GBS6 in the previous study. Participants who received placebo in the previous study were not included in this study. Pregnant women did not participate in this study. 152 participants were randomized in the study. One participant did not receive vaccine, therefore a total of 151 participants received GBS6 in this study.

This study, an extension to a completed study, evaluated the safety and tolerability from a booster vaccine dose of GBS6. This study vaccine was given approximately 2 years after a primary GBS6 dose to healthy adult males and non-pregnant women.

- A total of 37 (25%) men participated
- A total of 114 (76%) women participated
- Participants were between the ages of 20 years and 52 years

Of the 151 participants who started the study, 149 (99%) finished the study.

2 participants did not finish the study because they were lost to follow-up. Lost to follow-up means that the participant did not return for clinic visits and did not respond to phone calls from the study site staff.

No participants withdrew from the study or were asked to withdraw by the study staff or the Sponsor.

How long did the study last?

Study participants were in the study for 6 months. The entire study took about 7 months to complete.

The trial began in February 2020 and was completed in September 2020, which included the period when the COVID-19 pandemic was occurring globally. The study was completed despite the impact of the pandemic and the study objectives were achieved. A decision was made to stop enrollment of participants for 3 weeks between March 2020 and April 2020. It was then decided by the study team that enough participants were randomized and that no more participants would be added. Further study visits were performed with minimal impact to the study.

When the study ended in September 2020, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What medical problems did participants have during the study?

The researchers recorded any medical problems the participants had during the study. Participants could have had medical problems for reasons not related to the study (for

example, caused by an underlying disease or by chance). Medical problems could also have been caused by the study vaccine or by another medicine the participant was taking. Sometimes the cause of a medical problem is unknown. By comparing medical problems across many groups in many studies, doctors try to understand what effects a study vaccine might have on a participant.

113 out of 151 (75%) participants in this study had at least 1 non-serious medical problem within 1 month after vaccination. Of the 76 participants who received GBS6 with $AlPO_4$, 59 participants (78%) reported a non-serious medical problem. Of the 75 participants who received GBS6 without $AlPO_4$, 54 participants (72%) reported a non-serious medical problem. No participants left the study because of medical problems. The most common non-serious medical problems – those reported by more than 10% of participants – are described below.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists non-serious medical problems that were commonly reported during the study. All non-serious medical problems reported by more than 10% of participants are listed.
- The **2nd** column tells how many of the 76 participants taking GBS6 with $AlPO_4$ reported each medical problem. Next to this number is the percentage of the 76 participants taking GBS6 with $AlPO_4$ who reported the medical problem.
- The **3rd** column tells how many of the 75 participants taking GBS6 without $AlPO_4$ reported each medical problem. Next to this number is the percentage of the 75 participants taking GBS6 without $AlPO_4$ who reported the medical problem.
- Using these instructions, you can see that 52 out of the 76 participants (68%) taking the GBS6 with $AlPO_4$ reported pain where vaccine was injected. A total of 32 out of the 75 (43%) participants taking GBS6 without $AlPO_4$ reported pain where vaccine was injected.

Table 1. Commonly reported non-serious medical problems by study participants within 1 month after vaccination		
Medical Problem	**GBS6 with $AlPO_4$ (76 Participants)**	**GBS6 without $AlPO_4$ (75 Participants)**
Pain where vaccine was injected	52 out of 76 participants (68%)	32 out of 75 participants (43%)
Feeling tired	34 out of 76 participants (45%)	23 out of 75 participants (31%)
Headache	23 out of 76 participants (30%)	31 out of 75 participants (41%)
Muscle pain	18 out of 76 participants (24%)	13 out of 75 participants (17%)
Loose stools	12 out of 76 participants (16%)	12 out of 75 participants (16%)
Joint pain	9 out of 76 participants (12%)	7 out of 75 participants (9%)
Throwing up	6 out of 76 participants (8%)	8 out of 75 participants (11%)

Did study participants have any serious medical problems?

A medical problem is considered "serious" when it is life-threatening, needs hospital care, or causes lasting problems.

1 participant (1%, or 1 out of 151 participants) had a serious medical problem during the study.

- 1 participant in the GBS6 with $AlPO_4$ group had a serious medical problem (thermal burn) during the study.
- No participants in the GBS6 without $AlPO_4$ had a serious medical problem during the study.

Researchers do not believe the serious medical problem reported by the participant was related to study vaccine. No participants passed away during the study.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the doctor or staff at your study site. For more details on your study protocol, please visit:
www.clinicaltrials.gov Use the study identifier **NCT04258995**

Please remember that researchers look at the results of many studies to find out which vaccines can work and are safe for study participants.

Again, if you participated in this study,
thank you for volunteering.
We do research to try to find the
best ways to help study participants, and you
helped us to do that!