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: BioNTech SE

Sponsor Agent: Pfizer Inc.

Vaccine(s) Studied: PF-07302048 (BNT162b2)

Protocol Number: C4591005

Dates of Study: 21 October 2020 to 25 November 2021

Title of this Study: Study to Evaluate the Safety, Tolerability, and Immunogenicity of an RNA Vaccine Candidate Against COVID-19 in Healthy Japanese Adults

[Final Report: A Phase 1/2, Placebo-Controlled, Randomized, and Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a SARS-CoV-2 RNA Vaccine Candidate Against COVID-19 in Healthy Japanese Adults]

Date(s) of this Report: 27 December 2022

– Thank You –

If you participated in this study, Pfizer, the Sponsor agent, 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 COVID-19?

A new respiratory disease appeared in Wuhan, China in December 2019 and has since rapidly spread to many other countries around the world. In January 2020, the cause of this disease was found to be a new Coronavirus; and the disease it causes was named COVID-19 (Coronavirus disease 2019).

People can get COVID-19 through contact with another person who has the virus. COVID-19 is mainly a disease of the respiratory system, but it can also affect other organs in the body. COVID-19 can cause a wide range of symptoms, such as fever, cough, shortness of breath, and loss of sense of taste or smell. COVID-19 symptoms can sometimes be severe.

What are BNT162b2 RNA-Based COVID-19 Vaccines?

A vaccine is used to help the body to fight off germs. After a vaccine is injected into a person's body, the body responds by making "antibodies", which are proteins that fight infections and help to prevent disease. This is known as the body's "immune response".

The BNT162b2 investigational vaccine does not contain the whole virus, or the parts of the virus that can cause COVID-19. Instead, BNT162b2 is made up of part of the virus's genetic code, surrounded by fatty particles called lipids. It uses the body's own cells to produce a "spike protein". This spike protein may help the body to produce antibodies to fight against COVID-19.

At the time this study began, BNT162b2 was an investigational vaccine and it was not approved for general use. BNT162b2 has now been approved for use in Japan and other countries. An initial course of BNT162b2 is given as 2 doses, about 3 weeks apart.

What was the purpose of this study?

The main purpose of this study was to learn about the safety and about the body's immune response to the BNT162b2 vaccine, in healthy Japanese adults.

Researchers wanted to know:

Did participants have an immune response against the virus that can cause COVID-19?

How many participants had pain, redness, or swelling at the injection site within 7 days after vaccination?

How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after vaccination?

How many participants had any medical problems within 1 month after their second vaccination?

How many participants had serious medical problems within 12 months after their second vaccination?

How many participants from a clinical laboratory subset had abnormal blood test results 1 and 7 days after their first vaccination and 7 days after their second vaccination?

What happened during the study?

How was the study done?

Researchers studied 2 groups of study participants. Each participant was planned to receive either 2 doses of the BNT162b2 vaccine or 2 doses of placebo, given about 3 weeks apart. A placebo does not have any vaccine in it, but it looks similar to the study vaccine.

- Group 1 (119 participants): BNT162b2 vaccine
- Group 2 (41 participants): Placebo

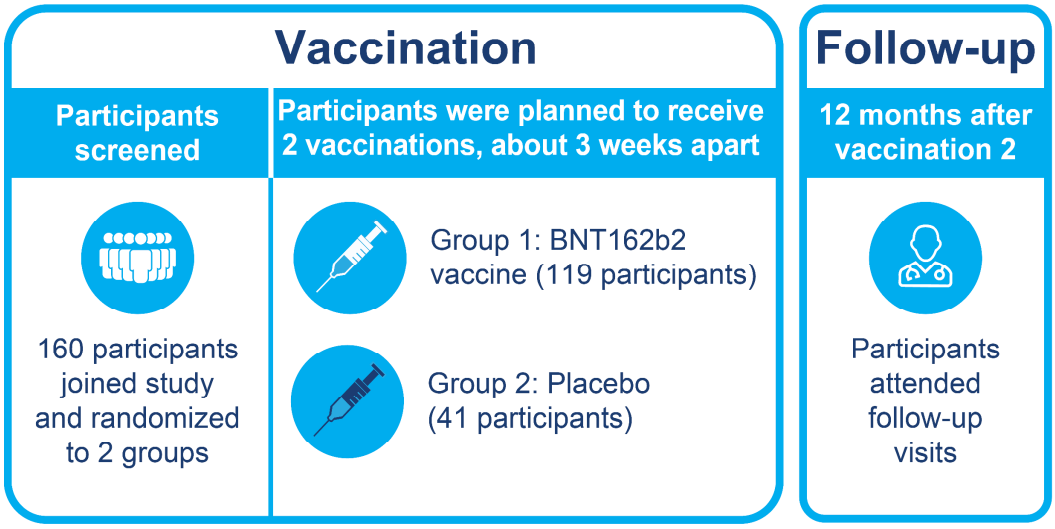
This was as an "observer blinded" study, which means that the researchers and the participants did not know if they received the vaccine or placebo, but the healthcare workers who prepared and administered the study vaccines did know. Study participants were assigned to each group by chance alone.

Participants were first screened by a doctor to make sure they met the requirements to join the study. This was known as the screening period. Participants were in the study for about 12 months, and were expected to attend at least 7 visits at the study center during this time. At these visits, participants received study vaccines, had their blood drawn and other lab samples collected, and were monitored for any medical problems. The study was changed after it started to allow participants who originally received the placebo to receive the BNT162b2 vaccine. These participants were then checked for safety for 6 months after their second dose of the vaccine.

The first 24 participants who joined the study (12 participants aged 20 to 64 and 12 participants aged 65 to 85) were also enrolled in the "clinical laboratory subset". These participants had additional blood tests done.

Figure 1 below shows what happened during the study.

Figure 1. What happened during the study?



Where did this study take place?

The Sponsor ran the study at 2 locations in Japan.

When did this study take place?

It began 21 October 2020 and ended 25 November 2021.

Who participated in this study?

Japanese participants 20 to 85 years of age could join the study. Study participants:

- Were examined by the study doctor and determined to be appropriate for study participation
- Had never been diagnosed with COVID-19
- Had never received a COVID-19 vaccine outside of this study
- Were not allergic to any of the ingredients in the study vaccines
- Were not pregnant or breast-feeding

- A total of 81 men (51%) participated
- A total of 79 women (49%) participated
- 130 participants (81%) were 20 to 64 years of age
- 30 participants (19%) were 65 to 85 years of age

A total of 160 participants joined the study, and 157 participants (98%) received both doses of study vaccine or placebo. 3 participants (2%) left the study early: 1 participant left because of a medical problem, 1 participant chose to leave the study, and 1 participant had a "protocol deviation" (study procedures were not followed correctly).

A total of 35 out of 41 (85%) participants who were originally randomized to the placebo group also received both doses of BNT162b2.

How long did the study last?

Participants were in the study for about 1 year. The entire study took a little more than a year to complete.

When the study ended in November 2021, the Sponsor began reviewing the information collected. The Sponsor then created a first report of the results. This is a summary of that report.

What were the results of the study?

Did participants have an immune response against the virus that can cause COVID-19?

The researchers measured the amount of antibodies against the virus that can cause COVID-19 in participants' blood at the beginning of the study, and again 1 month after the second dose of BNT162b2 or placebo.

1 month after the second dose of BNT162b2, researchers saw a rise in antibodies among the participants who received BNT162b2. The amount of antibodies was lower in the older age group (65 to 85 years of age) compared with the younger age group (20 to 64 years of age). The researchers did not see a rise in antibodies among the participants who received placebo.

This does not mean that everyone in this study had these results. This is a summary of just some of the main results of this study. Other studies may have different results.

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). Or, medical problems could also have been caused by a 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 vaccine groups in many studies, doctors try to understand what effects a study vaccine might have on a participant.

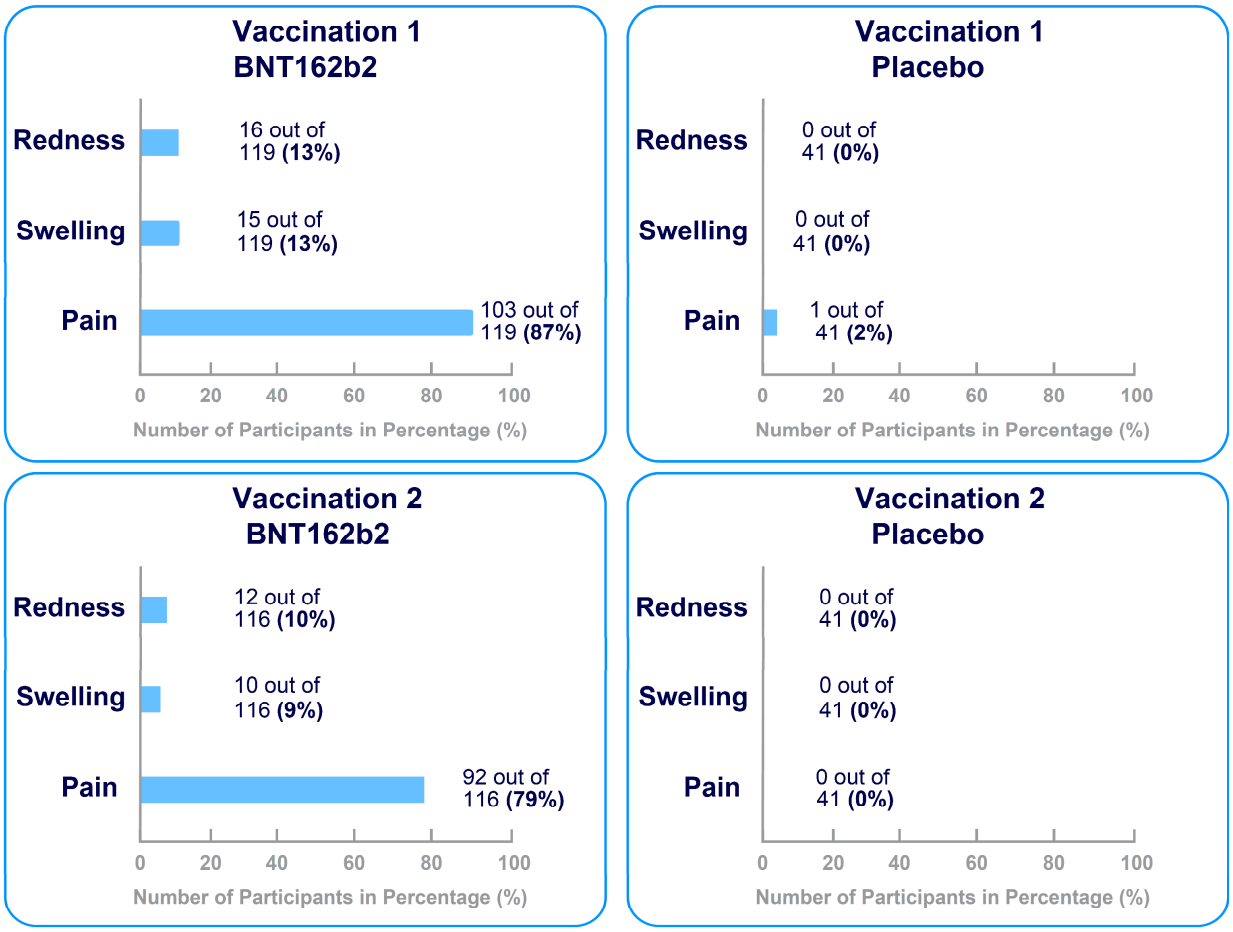
How many participants had pain, redness, or swelling at the injection site within 7 days after vaccination?

109 out of 119 (92%) participants who received BNT162b2 had redness, swelling, or pain at the injection site (or the skin area where the needle was injected) within 7 days of the first or second study vaccination. 1 (2%) participant who received placebo had pain at the injection site, and no participants who received placebo had redness or swelling at the injection site.

The charts below in **Figure 2** show that pain at the injection site was the most common reaction after both Vaccination 1 and Vaccination 2 in participants who

received BNT162b2.

Figure 2. How many participants had redness, swelling, or pain at the injection site within 7 days of each study vaccination?



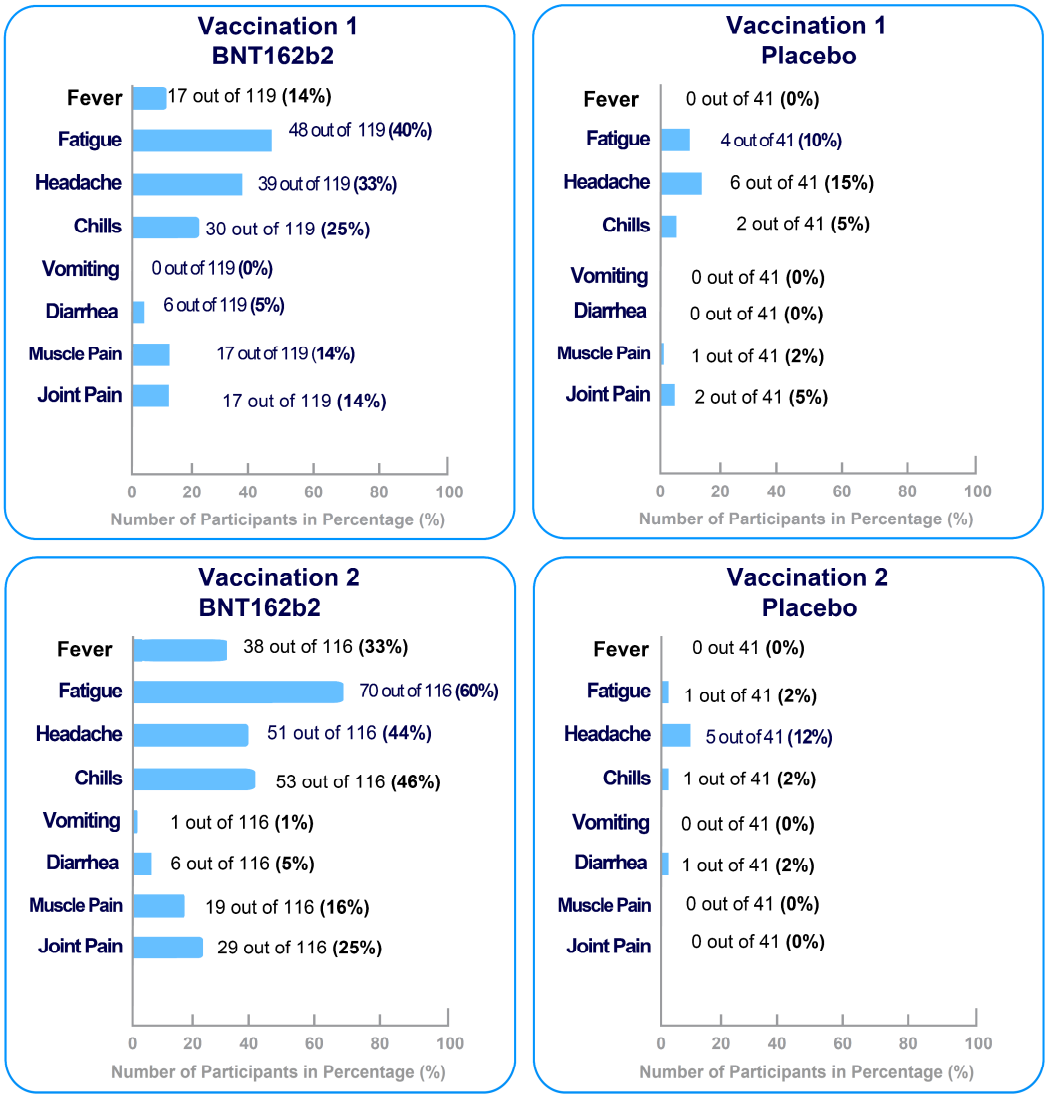
How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after vaccination?

93 out of 119 (78%) participants who received BNT162b2 and 9 out of 41 (22%) participants who received placebo had fever, tiredness, headache, chills, vomiting,

diarrhea, muscle pain, or joint pain within 7 days of study vaccination.

The charts in **Figure 3** below show that headache and fatigue were the most common symptoms.

Figure 3. How many participants had fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days of each study vaccination?



How many participants from a clinical laboratory subset had abnormal blood test results 1 and 7 days after their first vaccination and 7 days after their second vaccination?

Abnormal blood test results were uncommon, and almost all were considered to be mild in severity.

How many participants had any medical problems within 1 month after their second vaccination?

13 out of 119 (11%) participants in the BNT162b2 group and 3 out of 41 (7%) participants in the placebo group had a medical problem from Dose 1 to one month after Dose 2.

1 participant in the BNT162b2 group left the study because of medical problems that were considered to be related to the study vaccine (chills, tiredness, headache, joint pain, and injection site pain).

The table below describes the most common medical problems – those reported by at least 2 participants in either group.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists the most common medical problems reported during the study. It lists all medical problems reported by at least 2 participants in either group.
- The **2nd** and **3rd** columns tell how many of the participants in each group had a medical problem. Next to this number is the percentage of participants in either group who had the medical problem.

- Using these instructions, you can see that 3 out of 119 participants (3%) who received BNT162b2 had common cold. 1 out of 41 (2%) participants who received placebo had common cold.

Table 1. Most common medical problems reported by study participants (at least 2 participants in either group)

Medical Problem	BNT162b2 (119 participants)	Placebo (41 participants)
Common cold	3 out of 119 participants (3%)	1 out of 41 participants (2%)
Headache	2 out of 119 participants (2%)	1 out of 41 participants (2%)

Did study participants have any serious medical problems?

How many participants had serious medical problems within 12 months after their second vaccination?

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

2 out of 119 (2%) participants who received BNT162b2 had a serious medical problem during the study: 1 participant had pneumonia and 1 participant had cancer of the ovary. Neither of these serious medical problems were considered to be related to the vaccine. No participants died 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 **NCT04588480**

www.pfizer.com/research/research_clinical_trials/trial_results
Use the protocol number **C4591005**

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!