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 patients. 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 Studied:	Comirnaty® (BNT162b2 RNA-Based COVID-19 Vaccine, PF-07302048)
Protocol Number:	C4591031 Substudy B
Dates of Study:	20 December 2021 to 29 November 2022
Title of this Study:	A Study to Learn if a Booster Dose of BNT162b2 Was Safe in Healthy Children and Adults who Previously Received BNT162b2 [Substudy B Final Report: A Phase 3 Master Protocol to Evaluate Additional Dose(s) of BNT162b2 in Healthy Individuals Previously Vaccinated With BNT162b2]
Date of this Report:	07 September 2023

– Thank You –

If you or your child participated in this study, Pfizer, the Sponsor agent, would like to thank you or your child 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?

"Coronavirus disease 2019" (or COVID-19) is caused by a virus called **s**evere **a**cute **r**espiratory **s**yndrome **co**rona**v**irus **2** (SARS-CoV-2). People can catch COVID-19 from an infected person who has the virus, even if that person has no symptoms.

COVID-19 can cause a wide range of symptoms, such as fever, chills, cough, loss of taste or smell, and trouble breathing. Most people with COVID-19 have mild to moderate symptoms. But in some people, COVID-19 can be more severe, and they may need hospital care.

What is BNT162b2?

BNT162b2 (also called Comirnaty®) is an injectable vaccine that may help the body's immune system to defend against COVID-19.

- It does not contain a whole virus or any part of the virus that can cause COVID-19.
- It is made up of a 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", which may help the body to produce antibodies to fight against COVID-19.

In this study, BNT162b2 is the original "monovalent" COVID-19 vaccine. This "monovalent" vaccine contains RNA that targets the original strain of the COVID-19 virus.

What was the purpose of this study?

The main goal of this study was to find out if a BNT162b2 booster dose was safe and well tolerated by participants who previously received 2 or 3 doses of BNT162b2.

Researchers wanted to know:

- **How many participants had high troponin I levels after vaccination?**
- **What medical problems did participants have during the study?**

Troponin I is a marker in the blood that can rise when there is a heart injury.

What happened during the study?

How was the study done?

Researchers tested a third or fourth dose of BNT162b2 in a group of participants to see if it was safe and well tolerated. Participants were between 12 years and 30 years old and previously received 2 or 3 doses of BNT162b2.

All participants received 1 booster dose of BNT162b2 and 1 dose of placebo. A placebo does not have active ingredients in it and will cause no effect. They received each dose at 1 month apart.

Which study vaccine the participants got at each visit depended on which group they were randomly assigned (by chance) to at Visit 1.

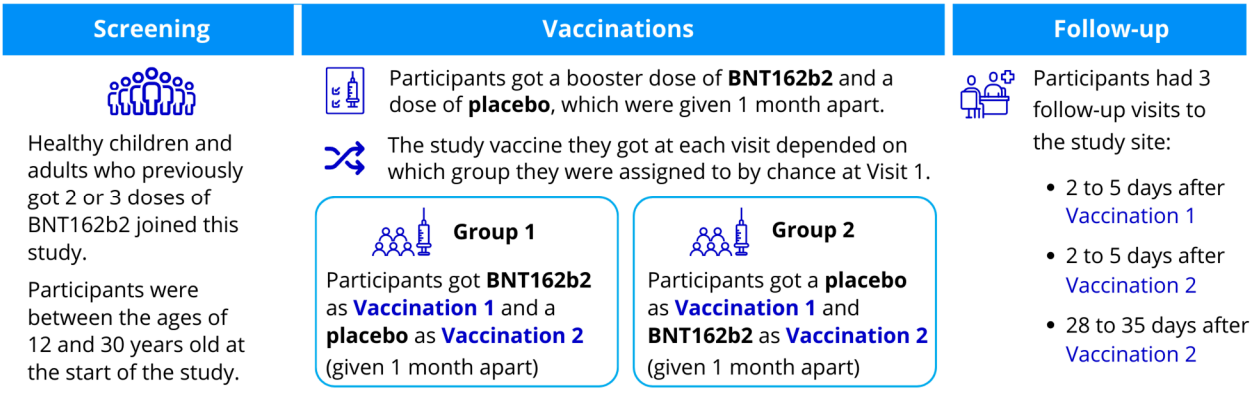
- **Group 1:** Participants would get BNT162b2 as Vaccination 1 and placebo as Vaccination 2.
- **Group 2:** Participants would get placebo as Vaccination 1 and BNT162b2 as Vaccination 2.

Researchers then compared the results of participants after they got BNT162b2 to the results of the same participants after they got a placebo.

The study was "observer-blinded". This means the healthcare staff who prepared and gave the vaccine knew which vaccine was given, but the study participants and researchers did not know.

Figure 1 below shows what happened in this study.

Figure 1: What happened in this study?



Where did this study take place?

The study ran at 45 locations in 3 countries (United States, Germany, and South Africa).

When did this study take place?

It began 20 December 2021 and ended 29 November 2022.

Who participated in this study?

The study included healthy children and adults aged between 12 years and 30 years old who have gotten 2 or 3 doses of BNT162b2 before joining this study. Their last dose of BNT162b2 must have been at least 4 months before the start of this study.

Of the 1487 participants who started the study, 1485 got at least 1 booster dose of BNT162b2 or a placebo.

- 604 boys or men participated.
- 881 girls or women participated.

A total of 1419 participants completed the study.

Sixty-six (66) participants left before the study was over. The most common reason participants left the study was by their choice.

How long did the study last?

Study participants were in the study for about 2 months. The entire study took about 11 months to complete.

When the study ended in November 2022, the Sponsor agent began reviewing the information collected. The Sponsor agent then created a report of the results. This is a summary of that report.

What were the results of the study?

How many participants had high troponin I levels after vaccination?

Troponin I is a marker in the blood that can rise when there is a heart injury.

About **2 to 5 days after they got BNT162b2 or placebo**, few participants had high troponin I levels:

- 9 out of 1353 participants (1%) after they got BNT162b2.
- 14 out of 1360 participants (1%) after they got placebo.

About **1 month after they got BNT162b2 or placebo**, few participants had high troponin I levels:

- 9 out of 1273 participants (1%) after they got BNT162b2.
- 7 out of 1276 participants (1%) after they got placebo.

The above results showed no differences in how many participants had high troponin levels at 2 to 5 days and 1 month after they got BNT162b2 or 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 redness, swelling, or pain at the injection site within 7 days after vaccination?

The following participants had any redness, swelling, or pain at the injection site within 7 days after they got BNT162b2 or placebo:

- 1048 out of 1419 participants (74%) after they got BNT162b2.
- 171 out of 1434 participants (12%) after they got placebo.

Most of these injection site reactions were mild to moderate and went away within an average of 1 to 2 days after onset. Injection site pain was the most common of these reactions.

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

The following participants had any fever, tiredness, headache, chills, vomiting, diarrhea, muscle pain, or joint pain within 7 days after they got BNT162b2 or placebo:

- 944 out of 1419 participants (67%) after they got BNT162b2.
- 550 out of 1434 participants (38%) after they got placebo.

Most of these symptoms were mild to moderate and went away within an average of 1 to 2 days after onset. Tiredness, headache, muscle pain, and chills were the most common of these symptoms.

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

The following participants had at least 1 medical problem within 1 month after they got BNT162b2 or placebo:

- 123 out of 1453 participants (8%) after they got BNT162b2.
- 117 out of 1463 participants (8%) after they got placebo.

A total of 10 participants left the study because of medical problems.

The most common medical problems – those seen in at least 1% of participants within 1 month after they got BNT162b2 or placebo – are described below.

- A positive test for COVID-19 virus happened in:
  - 18 out of 1453 participants (1%) after they got BNT162b2.
  - 26 out of 1463 participants (2%) after they got placebo.
- Injection site pain happened in:
  - 17 out of 1453 participants (1%) after they got BNT162b2.
  - 3 out of 1463 participants (less than 1%) after they got placebo.

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.

How many participants had serious medical problems within 1 month after vaccination?

In total, 5 serious medical problems happened in 4 participants within 1 month after they got BNT162b2 or placebo. These were seen in:

- 2 out of 1453 participants (less than 1%) after they got BNT162b2.
    - 1 participant had a bacterial skin infection.
    - 1 participant had a short-lived loss of consciousness after a head injury and a type of headache called migraine.
- 2 out of 1463 participants (less than 1%) after they got placebo.
    - 1 participant had a rare type of cancer that forms in soft tissue.
    - 1 participant had a miscarriage.

Researchers do not believe any of the serious medical problems reported by participants were related to the study vaccines.

No participants died during the study.

Where can I learn more about this study?

If you or your child 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.pfizer.com/research/research_clinical_trials/trial_results	Use the protocol number **C4591031 Substudy B**

The full scientific report of this study is available online at:

www.clinicaltrials.gov	Use the study identifier **NCT04955626**
www.clinicaltrialsregister.eu	Use the study identifier **2021-005197-25**

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

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