Plain Language Clinical Study

Summary

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: Pfizer Inc.

Vaccine(s) Studied: PF-07911145 (VZV modRNA Vaccine)

Protocol Number: C5031001

Dates of Study: 25 January 2023 to 19 September 2025

Title of this Study: A Study to Learn About a Modified RNA Vaccine Against Shingles in Healthy Adults

[A Phase 1/2 Randomized, Observer-Blind Study to Evaluate the Safety, Tolerability, and Immunogenicity of a Modified RNA Vaccine Against Varicella Zoster Virus in Healthy Individuals]

Date(s) of this Report: 27 August 2026

– Thank You –

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

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

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

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

Why was this study done?

What is shingles?

Shingles is caused by the same virus that gives you chickenpox called varicella zoster virus (VZV). Once you have had chickenpox, the virus stays in your body and can "wake up" years later as shingles.

Shingles usually shows up as a rash that appears in a band or as a patch of blistering rash on one side of the body (often the chest or face). Shingles can be quite painful, tingly, or itchy. Some people also feel unwell or have a headache.

Shingles isn't usually dangerous, but it can be very painful, and in some cases, the pain can last even after the rash heals. Sometimes, shingles can be dangerous in people who have a weakened immune system or when it appears near the eye and requires immediate medical attention to prevent vision loss.

What is VZV modRNA Vaccine?

This study is about a vaccine called VZV modRNA vaccine. A vaccine is used to help prevent infection by helping the body to fight off germs. VZV modRNA vaccine may be able to help stop the varicella zoster virus from waking up and causing shingles. The vaccine is given as an injection using a needle into your muscle.

What was the purpose of this study?

The purpose of this study was to learn about the safety of the VZV modRNA vaccines and if they were well tolerated.

This study used different vaccine candidates. Each vaccine candidate had a slightly different structure. The study also used Shingrix which is already available as a vaccine against shingles. The study also used a placebo which does not have any vaccine in it, but it looks just like the study vaccine. This placebo is saltwater.

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

This was done to make sure no one knew which vaccine was given and so that each participant received 2 vaccinations.

This study was planned to have a Part A and a Part B. However, Part B was never started due to a Sponsor decision. This decision was not based on any safety or tolerability concerns.

Researchers wanted to know:

- **Did the participants experience any pain, redness, or swelling where the injection was given?**
- **Did the participants experience any fever, tiredness, headache, chills, vomiting, diarrhea, new or worsened muscle pain, or new or worsened joint pain after the injection was given?**
- **What medical problems did participants have during the study?**

What happened during the study?

How was the study done?

First, researchers checked each participant to make sure they were able to join the study. This is known as screening.

This study tested 3 types of VZV modRNA vaccines, known as Candidate 1, Candidate 2, and Candidate 3. Some participants were given 1 of the 3 types of VZV modRNA vaccines, and some participants were given Shingrix. Sometimes, the vaccines were given at 0 and 2 months, at 0 and 6 months, or at 0 months with placebo or a saltwater injection given at 6 months.

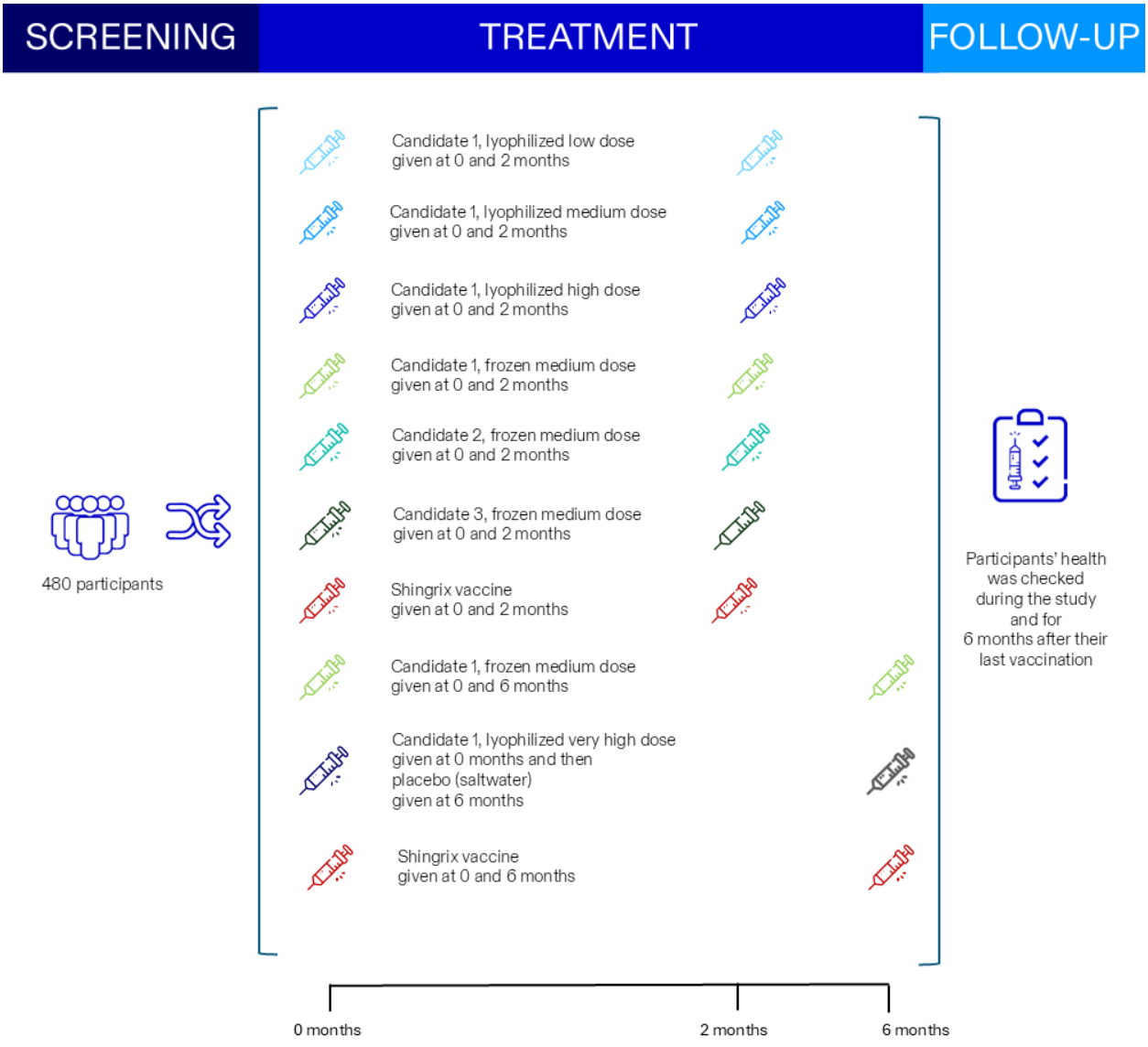
In total, there were 10 different vaccine options a participant could be given. The options differed in how strong the dose was (low, medium, high, or very high), how the vaccine was prepared (lyophilized or frozen), and when the vaccinations

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

were given (0 and 2, 0 and 6, or 0 months only). Lyophilized means that the vaccine was freeze dried. This process uses freezing to remove the water from the vaccine.

Figure 1 shows what happened during the study.

Figure 1. What happened in the study



090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

Researchers tested the different vaccine candidates and the Shingrix vaccine on a group of healthy participants to learn how safe and well-tolerated the vaccines were.

Participants were assigned by chance alone ("randomized") to be given one of the vaccines as an injection into the arm. The researchers did not know who was given which vaccine. This is known as an "observer-blinded" study.

After vaccination, the participant kept a diary for 7 days where they recorded any problems they were having. This included problems at the injection site.

Researchers looked to see if the participants had any fever, chills, diarrhea, vomiting, headache, tiredness, muscle pain, or joint pain for 7 days after being given the vaccine. Participants then received a 2nd injection of the vaccine candidate or the Shingrix vaccine. This was given either 2 months or 6 months later. Researchers also checked to see if the participants had any medical problems for up to 6 months after this last dose of vaccine.

Researchers also checked the participants' health during the study and asked them how they were feeling.

Researchers then compared the results of participants taking the different types of vaccine.

Where did this study take place?

The Sponsor ran this study at 27 locations in the United States.

When did this study take place?

It began 25 January 2023 and ended 19 September 2025.

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

Who participated in this study?

The study included healthy male or female participants aged 50 years and over who had not previously had shingles or received a varicella or herpes zoster vaccine.

- A total of 189 men participated.
- A total of 291 women participated.
- All participants were between the ages of 50 years and 69 years.

Of the 480 participants who were vaccinated, 480 received the 1st vaccination and 463 received the 2nd vaccination. There were 20 participants withdrawn from treatment. Reasons for being withdrawn from treatment included medical problems, death, withdrawal by participant, lost to follow-up, and the participant was no longer eligible for the study. Lost to follow-up means that the study center was not able to contact the participant.

How long did the study last?

Study participants were expected to be in the study for up to 5 years depending on the group they were assigned to. Since the study was stopped before planned end date, the entire study took around 2 years and 8 months to complete.

When the study ended in September 2025, the Sponsor began reviewing the information collected. The Sponsor then created a report of the results. This is a summary of that report.

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

What were the results of the study?

Did the participants experience any pain, redness, or swelling where the injection was given?

Participants were given diaries to record any pain, redness, or swelling in the area where the injection was given. This was done for 7 days after the vaccination. These types of reactions are called “local reactions”.

Vaccine Dosing Schedule: 0 and 2 Months Apart

After the 1st vaccination, local reactions in participants were similar between most of the candidate vaccine groups. More local reactions were recorded in the Shingrix group than in the other vaccine groups. Injection site pain was the most commonly reported local reaction in all vaccine groups.

After the 2nd vaccination, local reactions were generally similar between all vaccine groups. Injections site pain was the most commonly reported local reaction in all vaccine groups. Slightly more local reactions were seen in participants in the Shingrix group and the Candidate 1 lyophilized high dose group than in the other candidate vaccine groups.

Vaccine Dosing Schedule: 0 and 6 Months Apart

After the 1st vaccination, injection site pain was the most commonly reported local reaction in all vaccine groups. Slightly fewer participants reported injection site pain in the candidate vaccine groups than in the Shingrix group. Reports of redness were highest in the Shingrix group followed by Candidate 1 frozen medium dose and redness did not occur in the Candidate 1 lyophilized very high dose group. There were more reports of swelling in the Candidate 1 lyophilized very high dose group than in the Shingrix group and this was lowest in the Candidate 1 frozen medium dose group.

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

After the 2nd vaccination, injection site pain was the most commonly reported local reaction, with lower reports in participants in the Candidate 1 lyophilized very high dose group who were given saltwater as a placebo. Reports of redness and swelling were higher in the Shingrix group than in the Candidate 1 frozen medium dose group. Redness and swelling were not seen in participants in the Candidate 1 lyophilized very high dose group who were given saltwater as a placebo.

Did the participants experience any fever, tiredness, headache, chills, vomiting, diarrhea, new or worsened muscle pain, or new or worsened joint pain after the injection was given?

Participants were given diaries to record any fever, tiredness, headache, chills, vomiting, diarrhea, new or worsened muscle pain, or new or worsened joint pain for 7 days after being given the vaccination. These types of reactions are called "systemic events".

Vaccine Dosing Schedule: 0 and 2 Months Apart

Within 7 days after the 1st vaccination, tiredness and headache were the most commonly reported systemic events in participants in all vaccine groups. Reported systemic events were similar between the candidate vaccine groups and the Shingrix group apart from muscle pain, which was reported slightly more often in the Shingrix group.

Within 7 days after the 2nd vaccination, tiredness, headache, muscle pain, and chills were the most commonly reported systemic events in participants in all vaccine groups. Reported events were similar between the candidate vaccine groups and the Shingrix group.

Vaccine Dosing Schedule: 0 and 6 Months Apart

Within 7 days after the 1st vaccination, tiredness, headache, and muscle pain were the most commonly reported systemic events in participants in all vaccine

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

groups. Overall, fewer systemic events were reported in the candidate vaccine groups than in the Shingrix group.

Within 7 days after the 2nd vaccination, tiredness, headache, muscle pain, and chills were the most commonly reported systemic events in participants in all vaccine groups. Overall, systemic events were similar in the frozen candidate vaccine group and the Shingrix group. Both groups had more systemic events than the lyophilized candidate vaccine group where saltwater was given as the 2nd vaccination.

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 unknown 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 treatment groups in many studies, researchers try to understand what effects a study vaccine might have on a participant.

A total of 162 out of 480 participants (33.8%) in this study had at least 1 medical problem from the 1st vaccination through 1 month after the 2nd vaccination. A total of 3 participants left the study because of medical problems.

In participants given an injection at 0 and 2 months, the most common medical problems reported by more than 5% of participants was COVID-19 infection followed by cough. The medical problem of COVID-19 infection was experienced by the following groups of participants:

- Candidate 1 lyophilized high dose, 2 out of 54 participants (3.7%).

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

- Candidate 1 frozen medium dose, 4 out of 50 participants (8.0%).
- Candidate 2 frozen medium dose, 2 out of 50 participants (4.0%).
- Shingrix, 2 out of 60 participants (3.3%).

The medical problem of cough was experienced by the following groups of participants:

- Candidate 1 lyophilized medium dose, 3 out of 50 participants (6.0%).
- Shingrix, 1 out of 60 participants (1.7%).

In participants given an injection at 0 and 6 months, the most common medical problems – those reported by more than 5% of participants in any group and when there was more than 1 participant with that medical problem in the group – are described in Table 1.

Below are instructions on how to read Table 1.

Instructions for Understanding Table 1.

- The first row of the table shows the groups in the study and the number of participants in each group.
- The blue and white rows in Table 1 show individual medical problems that were commonly reported by more than 5% of participants in any group and when there was more than 1 participant with that medical problem in the group.
- The 1st column of Table 1 tells how many of the 50 participants given Candidate 1 frozen at a medium dose at 0 and 6 months reported each medical problem. Below the number is the percentage of the 50 participants given this vaccine who reported the medical problem.
- The 2nd column of Table 1 tells how many of the 15 participants given Candidate 1 lyophilized at a very high dose at 0 months and then

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

saltwater at 6 months reported each medical problem. Below the number is the percentage of the 15 participants given this vaccine who reported the medical problem.

- The 3rd column of Table 1 tells how many of the 53 participants given the Shingrix vaccine at 0 and 6 months who reported each medical problem. Below the number is the percentage of the 53 participants who given the Shingrix vaccine and reported the medical problem.
- Using these instructions, you can see that 3 out of the 50 participants (6.0%) given the Candidate 1 frozen at a medium dose at 0 and 6 months reported injection site itching. None of the participants in other vaccine groups given vaccines at 0 and 6 months reported injection site itching.

Table 1. Commonly reported medical problems by study participants given an injection at 0 and 6 months

Candidate 1 frozen medium dose (50 participants)	Candidate 1 lyophilized very high dose/saltwater (15 participants)	Shingrix (53 participants)
Injection site itching		
3 out of 50 participants (6.0%)	0 participants	0 participants
Common cold (upper respiratory tract infection)		
1 out of 50 participants (2.0%)	2 out of 15 participants (13.3%)	3 out of 53 participants (5.7%)

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

Table 1. Commonly reported medical problems by study participants given an injection at 0 and 6 months

Candidate 1 frozen medium dose (50 participants)	Candidate 1 lyophilized very high dose/saltwater (15 participants)	Shingrix (53 participants)
COVID-19 infection		
2 out of 50 participants (4.0%)	2 out of 15 participants (13.3%)	1 out of 53 participants (1.9%)
Infection of the structures that carry urine (such as bladder), known as a urinary tract infection (UTI)		
3 out of 50 participants (6.0%)	0 participants	0 participants
Pain in the throat or mouth		
1 out of 50 participants (2.0%)	2 out of 15 participants (13.3%)	0 participants

There were 99 out of 480 participants (20.6%) who had medical problems that required a visit to a doctor's surgery or hospital. These visits were mostly due to infections.

The study did not identify any important findings in heart tests (electrocardiograms), troponin I levels, or other laboratory tests results in participants in the study. Troponin I can be used as a sign of heart damage.

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

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.

A total of 11 participants out of 480 participants (2.3%) had serious medical problems from the 1st vaccination to 6 months after the 2nd vaccination.

- Six (6) out of 50 participants (12.0%) in the Candidate 1 lyophilized medium dose group given the vaccine at 0 and 2 months had 8 serious medical problems:
    - Stroke and fast heartbeat in 1 participant.
    - Sudden inflammation in the pancreas in 1 participant.
    - Ankle fracture in 1 participant.
    - Fall in 1 participant.
    - Back pain and brain damage caused by reduced blood flow in 1 participant.
    - Thyroid cancer in 1 participant.
- Two (2) out of 60 participants (3.3%) in the Shingrix group given the vaccine at 0 and 2 months had 2 serious medical problems:
    - Fluid filled sac in the thymus gland in 1 participant.
    - A growth on or in the thyroid in 1 participant.

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

- Three (3) out of 50 participants (6.0%) in the Candidate 1 frozen medium dose group given the vaccine at 0 and 6 months had 4 serious medical problems:
    - Chest pain and high blood pressure in 1 participant.
    - Kidney infection in 1 participant.
    - Ovarian cancer in 1 participant.

None of these serious medical problems were thought to be related to the vaccines.

There was 1 participant who died during the study from the serious medical problem of brain damage caused by reduced blood flow. This serious medical problem was not thought to be due to the candidate vaccine.

Where can I learn more about this study?

If you have questions about the results of your study, please speak with the researcher 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 **C5031001**

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

www.clinicaltrials.gov

Use the study identifier **NCT05703607**

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

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

Pfizer

Again, if you 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!

090177e1a6de1a6a\Approved\Approved On: 28-Aug-2026 10:14 (GMT)

Pfizer