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: Abrysvo™, also known as respiratory syncytial virus stabilized prefusion F subunit (RSVpreF) vaccine

Protocol Number: C3671032

Dates of Study: 12 March 2024 to 11 June 2025

Title of this Study: A Study to Learn About the Vaccine RSVpreF in Pregnant Participants with HIV and Their Infants

[Final Report: A Phase 3, Randomized, Double-Blinded, Placebo-Controlled Trial to Evaluate the Safety, Tolerability, and Immunogenicity of Respiratory Syncytial Virus (RSV) Prefusion F Subunit Vaccine in Pregnant Participants Living with HIV and Their Infants]

Date(s) of this Report: 03 June 2026

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– Thank You –

If you or your child 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.

Why was this study done?

What is RSV?

Respiratory syncytial virus (RSV) is a virus that can cause an infection. Symptoms are similar to that of a bad cold, such as cough, fever, and runny nose. This infection can be serious in babies, older adults, and in those with underlying medical conditions such as human immunodeficiency virus (HIV). People with serious RSV infection may have trouble breathing and may need to be hospitalized. There is no specific treatment for RSV infection.

What is the RSV vaccine (RSVpreF)?

This study is about a vaccine called the respiratory syncytial virus vaccine, or "RSVpreF." A vaccine is used to help prevent infection by helping the body to fight off germs. RSVpreF may be able to help prevent infections caused by the 2 types of RSV. These are known as RSV A and RSV B.

RSVpreF contains proteins found in the virus that may stimulate the body's response to make antibodies (known as the "immune response" or "antibody response"), which may protect against RSV disease. There is no live virus in RSVpreF.

What was the purpose of this study?

RSVpreF has been shown to prevent RSV disease in babies born to pregnant women who are not living with HIV. These RSV infections occur deep in the chest and affect the lungs and airways. Pregnant women living with HIV are more likely to become infected with viruses like RSV. They are also more likely to experience harm from the RSV virus. The RSV virus is also more likely to infect their babies, and possibly even lead to death. This is because HIV can lower the immune response to respiratory infections, leaving both pregnant women and their babies less protected against RSV.

The study was done to look at how safe the RSVpreF vaccine was for pregnant women living with HIV and for their babies after birth. The study also looked at whether antibodies made by the vaccinated mothers could pass to their babies through the placenta before birth.

Researchers wanted to know:

- **Did the participant experience any pain, redness, and swelling where the injection was given within 7 days of vaccination?**
- **Did the participant experience fever, feeling sick in their stomach (nausea), diarrhea, vomiting, headache, tiredness, muscle pain, and joint pain within 7 days of vaccination?**
- **Did the baby have any changes to their health at birth or any long-term health conditions up to 6 months old?**
- **Did the mother or baby have any medical problems?**

What happened during the study?

How was the study done?

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

Participants were assigned by chance alone ("randomized") to be given either RSVpreF or placebo. A placebo does not have any vaccine in it, but it looks just like the study vaccination. The vaccine or the placebo were given as an injection

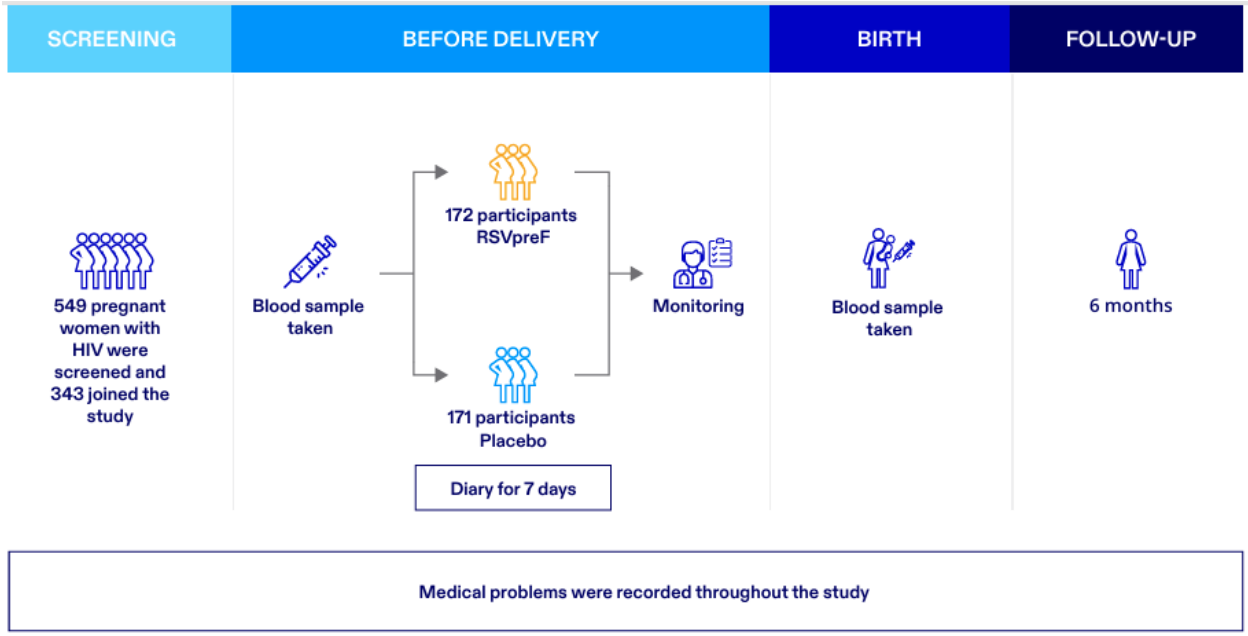
into the participant's arm muscle. The vaccine or placebo were not given to the babies in the study.

The study participants and researchers did not know who was given RSVpreF and who was given the placebo. This is known as a "blinded" study.

Participants had a blood sample taken before they were given the vaccine, then another blood sample taken soon after the birth of their baby. 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 including any pain, redness, and swelling.

Researchers looked to see if the participant had any fever, felt sick in their stomach (nausea), diarrhea, vomiting, headache, tiredness, muscle pain, and joint pain after being given the vaccine. Researchers also checked to see if the participant or their baby had any medical problems. Researchers monitored the participants and their babies at birth and for 6 months after the birth to see if how they were doing (Figure 1).

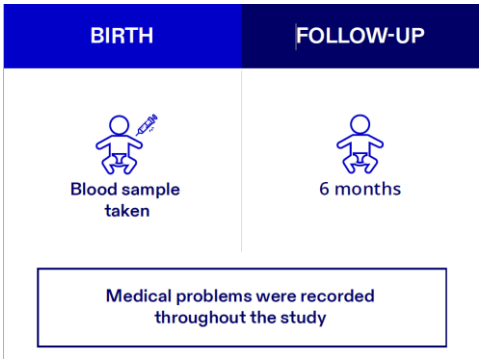
Figure 1. Study design for the pregnant participants (mothers) in the study



Pregnant women were assigned to 2 groups by chance and received either RSVpreF or placebo.

There were 338 babies born to the participants in the study, 171 to mothers who received RSVpreF and 167 to mothers who received placebo. At birth, babies had a blood sample taken. Babies were monitored for medical problems for 6 months after birth and any long-term health conditions were noted (Figure 2).

Figure 2. Study design for babies born to participants in the study



There were 338 babies born to the participants in the study, 171 to mothers who received RSVpreF and 167 to mothers who received placebo.

Where did this study take place?

The Sponsor ran this study at 14 locations in South Africa.

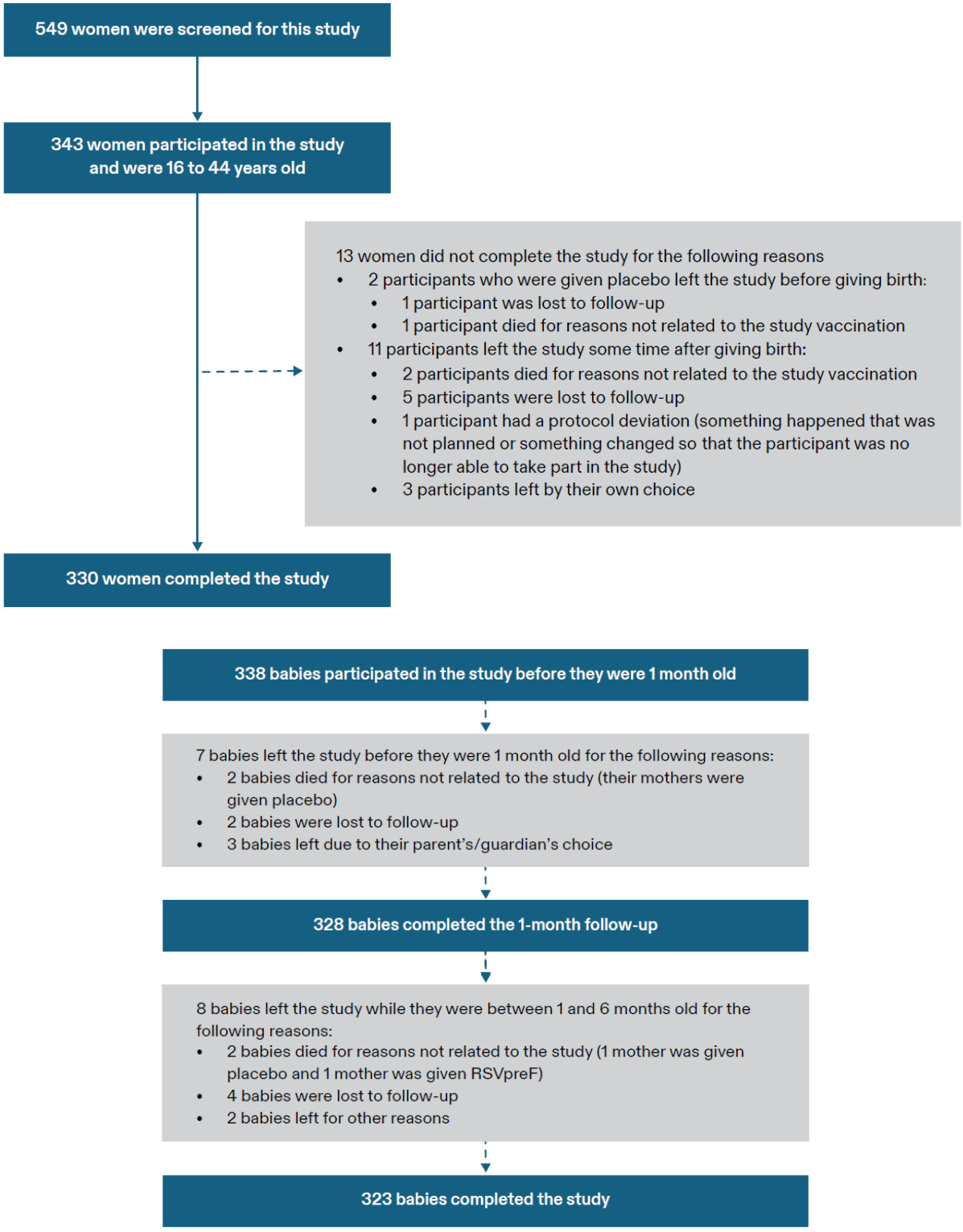
When did this study take place?

It began 12 March 2024 and ended 11 June 2025.

Who participated in this study?

The study included participants who were up to 49 years old and between 24 and 36 weeks pregnant with stable HIV (Figure 3). Stable HIV means the virus is under control with treatment and the person's health is not changing or worsening.

Figure 3. What happened to participants and their babies in the study



Note: Lost to follow-up means the participant could not be contacted to check on their health and/or the health of the baby.

How long did the study last?

Study participants were in the study for up to approximately 10 months. The entire study took 15 months to complete.

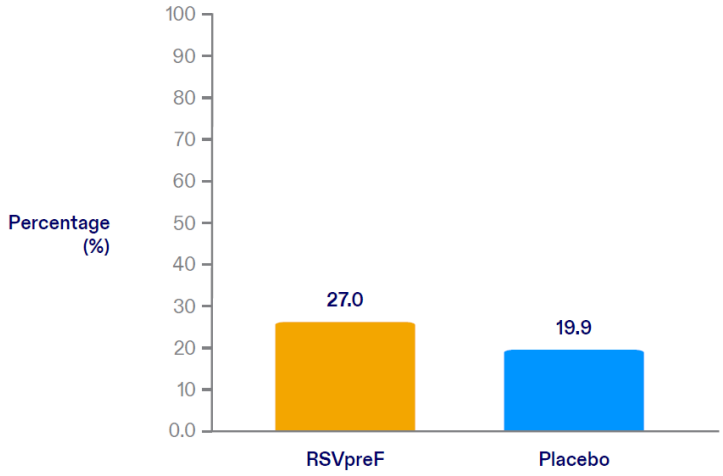
When the study ended in June 2025, the Sponsor began reviewing all of the information collected. The Sponsor then created a report of the results. This is a summary of that report.

What were the results of the study?

Did the participant experience any pain, redness, and swelling where the injection was given within 7 days of vaccination?

Participants were given diaries to record any pain, redness, and swelling where the injection was given for 7 days after being given the vaccination. These types of reactions are called "local reactions". Slightly more participants given RSVpreF reported local reactions than in the placebo group (Figure 4).

Figure 4. Local reactions after the RSVpreF or placebo injection

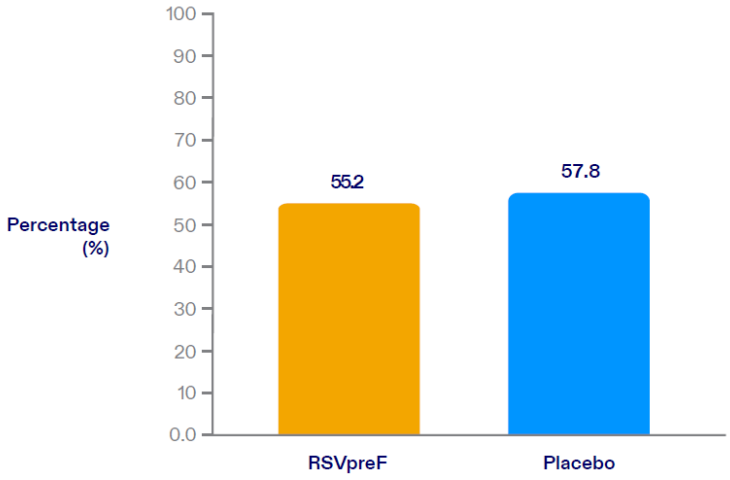


Pain was the most commonly reported local reaction, seen in 27.0% of participants given RSVpreF and 17.5% of participants given placebo.

Did the participant experience fever, feeling sick in their stomach (nausea), diarrhea, vomiting, headache, tiredness, muscle pain, and joint pain within 7 days of vaccination?

Participants were given diaries to record any fever, feeling sick in their stomach (nausea), diarrhea, vomiting, headache, tiredness, muscle pain, and joint pain for 7 days after being given the vaccination. These types of reactions are called "systemic reactions". Systemic reactions were generally similar in the RSVpreF and placebo groups (Figure 5).

Figure 5. Systemic reactions after the RSVpreF or placebo injection



Tiredness was the most commonly reported systemic reaction, seen in 35.0% of participants given RSVpreF and 41.6% of participants given placebo. The percentage of participants who had fever was low in both groups.

Did the baby have any changes to their health at birth or any long-term health conditions up to 6 months old?

Most babies were born at term and had a normal birthweight. The health of the babies at birth and the presence of any long-term health conditions up to 6 months old were similar between babies born to participants who were given

RSVpreF or placebo. Results for the medical problems up to 6 months are captured below.

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 treatment or by another vaccine 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.

Sixty-six (66) out of 342 participants (19.3%) in this study had at least 1 medical problem up to a month after being given the vaccination. No participants left the study because of medical problems. The most common medical problems – those reported by 2 or more participants in the RSVpreF or placebo groups – are described below.

Note: Data related to medical problems were not available for 1 participant who was given the placebo.

Below are instructions on how to read Table 1. Tables 2 to 5 can be read in a similar way.

Instructions for Understanding Table 1.

- The **1st** column of Table 1 lists medical problems that were commonly reported during the study. All medical problems reported by 2 or more participants in the RSVpreF or placebo groups are listed.
- The **2nd** column tells how many of the 172 participants who were given the RSVpreF vaccine reported each medical problem. Next to this number is the percentage of the 172 participants who were given the RSVpreF vaccine and reported the medical problem.
- The **3rd** column tells how many of the 170 participants who were given the placebo reported each medical problem. Next to this number is the percentage of the 170 participants who were given the placebo and reported the medical problem.
- Using these instructions, you can see that 2 out of the 172 participants (1.2%) who were given the RSVpreF vaccine reported low red blood cell count during pregnancy. None of the 170 participants who were given the placebo had this medical problem.

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Table 1. Commonly reported medical problems by study participants		
Medical Problem	**RSVpreF (172 Participants)**	**Placebo (170 Participants)**
Low red blood cell count during pregnancy	2 out of 172 participants (1.2%)	0 participants
Low red blood cell count	0 participants	2 out of 170 participants (1.2%)
Nose and throat infection	1 out of 172 participants (0.6%)	5 out of 170 participants (2.9%)
Infection of the structures that carry urine (such as the bladder), known as a "urinary tract infection", or "UTI"	4 out of 172 participants (2.3%)	3 out of 170 participants (1.8%)
Dizziness	4 out of 172 participants (2.3%)	1 out of 170 participants (0.6%)
The baby was showing signs of distress at birth	6 out of 172 participants (3.5%)	1 out of 170 participants (0.6%)
Baby's growth has been limited	2 out of 172 participants (1.2%)	1 out of 170 participants (0.6%)
High blood pressure during pregnancy	3 out of 172 participants (1.7%)	2 out of 170 participants (1.2%)

Table 1. Commonly reported medical problems by study participants		
Medical Problem	**RSVpreF (172 Participants)**	**Placebo (170 Participants)**
High blood pressure and protein in urine during pregnancy (pre-eclampsia)	1 out of 172 participants (0.6%)	3 out of 170 participants (1.8%)
Premature delivery of baby	7 out of 172 participants (4.1%)	5 out of 170 participants (2.9%)
Protein in the urine	0 participants	2 out of 170 participants (1.2%)
Vaginal discharge	2 out of 172 participants (1.2%)	4 out of 170 participants (2.4%)

A total of 132 out of 337 babies (39.2%) in this study had at least 1 medical problem up to a month after being born. Three (3) babies (0.9%) left the study because of medical problems. The most common medical problems from birth to 1 month – those reported by 2 or more babies whose mothers were in the RSVpreF or placebo groups – are described below in Table 2. Babies were given the same group as their mother, either RSVpreF or placebo.

Table 2. Commonly reported medical problems by study babies		
Medical Problem	**RSVpreF (171 Babies)**	**Placebo (166 Babies)**
A bulge near the belly button where the stomach muscles have not closed properly, present after delivery (congenital umbilical hernia)	2 out of 171 babies (1.2%)	5 out of 166 babies (3.0%)
Down syndrome	0 babies	2 out of 166 babies (1.2%)
A bulge near the belly button where the stomach muscles have not closed properly	2 out of 171 babies (1.2%)	0 babies
Infection of 1 or more of the pockets from which hair grows (follicle)	3 out of 171 babies (1.8%)	0 babies
Life-threatening infection in newborn	2 out of 171 babies (1.2%)	2 out of 166 babies (1.2%)
Positive HIV test	0 babies	2 out of 166 babies (1.2%)
Decreased weight	0 babies	2 out of 166 babies (1.2%)
Problem with how the baby's brain is working after birth	0 babies	2 out of 166 babies (1.2%)

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Table 2. Commonly reported medical problems by study babies		
Medical Problem	**RSVpreF (171 Babies)**	**Placebo (166 Babies)**
Bleeding in the brain	0 babies	2 out of 166 babies (1.2%)
Yellowing of the skin or the whites of the eyes in newborns (jaundice)	6 out of 171 babies (3.5%)	11 out of 166 babies (6.6%)
Low birth-weight	23 out of 171 babies (13.5%)	21 out of 166 babies (12.7%)
Baby poo in the waters surrounding the baby in the womb (meconium)	2 out of 171 babies (1.2%)	1 out of 166 babies (0.6%)
Premature baby (baby born early)	15 out of 171 babies (8.8%)	13 out of 166 babies (7.8%)
Baby smaller than most babies at the same point in pregnancy	2 out of 171 babies (1.2%)	4 out of 166 babies (2.4%)
Lump in belly button (umbilical granuloma)	2 out of 171 babies (1.2%)	1 out of 166 babies (0.6%)
Breathing difficulties due to breathing in poo in the waters during birth	0 babies	4 out of 166 babies (2.4%)

Table 2. Commonly reported medical problems by study babies		
Medical Problem	**RSVpreF (171 Babies)**	**Placebo (166 Babies)**
Blocked up nose	2 out of 171 babies (1.2%)	1 out of 166 babies (0.6%)
Difficulty breathing in newborn	7 out of 171 babies (4.1%)	3 out of 166 babies (1.8%)
Difficulty breathing in premature baby due to lungs being not properly developed	3 out of 171 babies (1.8%)	3 out of 166 babies (1.8%)
Mild breathing problems of short duration due to fluid in lungs	0 babies	5 out of 166 babies (3.0%)
Nappy/diaper rash	0 babies	3 out of 166 babies (1.8%)
Heat rash (prickly heat)	2 out of 171 babies (1.2%)	2 out of 166 babies (1.2%)
Rash	2 out of 171 babies (1.2%)	2 out of 166 babies (1.2%)

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 117 out of 342 participants (34.2%) had serious medical problems throughout the study. The most common serious medical problems - those reported by 2 or more participants in the RSVpreF or placebo groups – are described in Table 3 below.

Table 3. Commonly reported serious medical problems by study participants

Medical Problem	RSVpreF (172 Participants)	Placebo (170 Participants)
Baby presented feet or buttocks first, rather than head first (breech)	3 out of 172 participants (1.7%)	1 out of 170 participants (0.6%)
Baby’s head too large to be born vaginally	2 out of 172 participants (1.2%)	5 out of 170 participants (2.9%)
Contractions that did not cause delivery	0 participants	2 out of 170 participants (1.2%)
The baby was showing signs of distress at birth	25 out of 172 participants (14.5%)	22 out of 170 participants (12.9%)

Table 3. Commonly reported serious medical problems by study participants		
Medical Problem	**RSVpreF (172 Participants)**	**Placebo (170 Participants)**
Baby's growth has been limited	1 out of 172 participants (0.6%)	2 out of 170 participants (1.2%)
Big baby (baby weighs more than other babies born at the same point in pregnancy)	0 participants	2 out of 170 participants (1.2%)
High blood pressure during pregnancy	6 out of 172 participants (3.5%)	4 out of 170 participants (2.4%)
Baby is unable to move down for delivery	2 out of 172 participants (1.2%)	0 participants
More bleeding than normal after childbirth	2 out of 172 participants (1.2%)	1 out of 170 participants (0.6%)
High blood pressure and protein in urine during pregnancy (pre-eclampsia)	4 out of 172 participants (2.3%)	8 out of 170 participants (4.7%)
Premature delivery of baby	3 out of 172 participants (1.7%)	3 out of 170 participants (1.8%)
Early breaking of waters	3 out of 172 participants (1.7%)	0 participants

Table 3. Commonly reported serious medical problems by study participants		
Medical Problem	**RSVpreF (172 Participants)**	**Placebo (170 Participants)**
Prolonged labor	5 out of 172 participants (2.9%)	0 participants
Prolonged pregnancy	1 out of 172 participants (0.6%)	4 out of 170 participants (2.4%)
Prolonged breaking of waters	2 out of 172 participants (1.2%)	1 out of 170 participants (0.6%)
Baby died before birth (stillbirth)	1 out of 172 participants (0.6%)	2 out of 170 participants (1.2%)
Scarring on the uterus	2 out of 172 participants (1.2%)	2 out of 170 participants (1.2%)

A total of 54 out of 337 babies (16.0%) had serious medical problems within their 1st month. The most common serious medical problems - those reported by 2 or more babies in the RSVpreF or placebo groups – are described in Table 4 below.

Table 4. Commonly reported serious medical problems by study babies within their 1st month

Medical Problem	RSVpreF (171 Babies)	Placebo (166 Babies)
Down syndrome	0 babies	2 out of 166 babies (1.2%)
Life-threatening infection in newborn	2 out of 171 babies (1.2%)	1 out of 166 babies (0.6%)
Problem with how the baby's brain is working after birth	0 babies	2 out of 166 babies (1.2%)
Yellowing of the skin or the whites of the eyes in newborn (jaundice)	4 out of 171 babies (2.3%)	5 out of 166 babies (3.0%)
Low birth-weight	2 out of 171 babies (1.2%)	5 out of 166 babies (3.0%)
Premature baby (baby born early)	3 out of 171 babies (1.8%)	5 out of 166 babies (3.0%)
Breathing difficulties due to breathing in poo in the waters during birth	0 babies	2 out of 166 babies (1.2%)

Table 4. Commonly reported serious medical problems by study babies within their 1st month		
Medical Problem	**RSVpreF (171 Babies)**	**Placebo (166 Babies)**
Difficulty breathing in newborn	2 out of 171 babies (1.2%)	2 out of 166 babies (1.2%)
Difficulty breathing in premature babies due to lungs being not properly developed	3 out of 171 babies (1.8%)	3 out of 166 babies (1.8%)
Mild breathing problems of short duration due to fluid in lungs	0 babies	4 out of 166 babies (2.4%)

There were 20 babies (5.9%, or 20 out of 337 babies) who had serious medical problems from 1 to 6 months old. The most common serious medical problems - those reported by 2 or more babies in the RSVpreF or placebo groups – are described in Table 5 below.

Table 5. Commonly reported serious medical problems by study babies from 1 to 6 months old		
Medical Problem	**RSVpreF (171 Babies)**	**Placebo (166 Babies)**
Low red blood cell count	0 babies	2 out of 166 babies (1.2%)

Table 5. Commonly reported serious medical problems by study babies from 1 to 6 months old		
Medical Problem	**RSVpreF (171 Babies)**	**Placebo (166 Babies)**
Stomach flu	3 out of 171 babies (1.8%)	2 out of 166 babies (1.2%)
Lung infection known as (pneumonia)	2 out of 171 babies (1.2%)	1 out of 166 babies (0.6%)

The health of the participants was checked for certain medical problems during this study. These medical problems are described as 'of special interest'. This is because the researchers are interested in finding out if any of the participants developed any of the following conditions:

- Guillain-Barré Syndrome – a rare condition where the immune system attacks the body's own nerves, causing muscle weakness and numbness.
- A nerve condition called peripheral neuropathy which causes muscle weakness, numbness, and pain.
- A rapid, irregular heartbeat.
- Giving birth before 37 weeks of pregnancy.
- High blood pressure during pregnancy

The medical problems of special interest that were seen in participants between vaccination and the delivery were:

- High blood pressure during pregnancy (6 participants [3.5%] in participants who were given the RSVpreF vaccine; and 7 participants [4.1%] in participants who were given placebo).
- High blood pressure and protein in urine during pregnancy (pre-eclampsia) (3 participants [1.7%] in participants who were given the RSVpreF vaccine; and 4 participants [2.4%] in participants who were given placebo).

The medical problems of special interest that were seen in participants between delivery and 1 month after delivery were:

- High blood pressure during pregnancy (3 participants [1.7%] in participants who were given the RSVpreF vaccine; and 1 participant [0.6%] in participants who were given placebo).
- High blood pressure and protein in urine during pregnancy (pre-eclampsia) (1 participant [0.6%] in participants who were given the RSVpreF vaccine; and 4 participants [2.4%] in participants who were given placebo).
- Premature delivery (15 participants [8.7%] in participants who were given the RSVpreF vaccine; and 13 participants [7.6%] in participants who were given placebo).

A total of 3 participants died during the study. Researchers do not believe any of the deaths were related to the study vaccines.

There were 3 babies who died before birth (stillbirths) during the study. None of these stillbirths were believed by researchers to be related to the study vaccines.

A total of 4 babies died during the study. Researchers do not believe any of the deaths were related to the study vaccines.

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 C3671032

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

www.clinicaltrials.gov

Use the study identifier NCT06325657

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!

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