mRNA-1345-P101 RSV Study Overview

About the mRNA-1345-P101 RSV Study

The mRNA-1345-P101 RSV Study is evaluating the safety and immune response of an investigational vaccine, called mRNA-1345, to protect against respiratory syncytial virus (RSV) in children aged 12 months to less than 60 months.

Researchers will measure your child's immune response to the investigational vaccine by collecting blood samples. These samples will be tested for natural proteins that are called antibodies. Checking your child's antibody level helps researchers know how well the investigational vaccine is working.

Study Design

The mRNA-1345-P101 RSV Study is enrolling approximately 46 pediatric participants who are seropositive for RSV. A blood test during the screening period will confirm the presence of RSV to determine if your child is seropositive for RSV.

Participants will be randomized to receive either the investigational vaccine or a placebo. Each participant will receive three injections each given 56 days apart (at Day 1, Day 57, and Day 113). The total length of participation is approximately 16 months. While enrolled in the study, you and your child will need to attend study visits in person and via phone, and you must complete an electronic diary (eDiary).

About mRNA-1345

The investigational vaccine being tested in this study is called mRNA-1345. It is not made from a weakened or killed virus. Instead, it includes a man-made version of a molecule known as messenger ribonucleic acid (mRNA), which is thought to provide the body with instructions on how to potentially defend against the virus. mRNA makes a harmless protein that looks just like a virus, which triggers the body's immune system to create antibodies[1]. It is hoped that these antibodies then fight the virus. Through this natural process, the immune system may create the antibodies it needs if it ever encounters the real RSV virus.

The investigational vaccine breaks down naturally and does not stay in the body. This is the first time that mRNA-1345 is being tested in children; however, mRNA-1345 has previously been tested in hundreds of adults. Several other studies testing similar investigational mRNA vaccines are also in progress.

Why Vaccines Are Important for Children

Young children encounter thousands of germs every day. Many germs are harmless and can be easily fought off by a child's immune system. However, certain bacteria and viruses can cause serious infection or illness, especially in young children whose immune systems are not fully developed yet[2]. Vaccines, both traditional antigen (which use a weakened or killed virus) and mRNA, can offer your child the protection they need from many of these illnesses.

Many people, including those in pediatric medicine, endorse the use of mRNA vaccines because unlike traditional vaccines, mRNA vaccines do not contain the actual viruses. Research on mRNA vaccines has been happening for decades[3]. The most well-known example of mRNA technology is the COVID-19 mRNA vaccine. The investigational vaccine in this study uses the same mRNA technology as the COVID-19 mRNA vaccine.

Eligibility Criteria

- Be at least 12 months (one year) old but less than 60 months (five years) old
- Be in generally good health
- Have received routine age-appropriate immunizations
- Be seropositive for RSV
  - A blood test during the screening period will confirm the presence of RSV

Additional eligibility requirements apply, which the study doctor will explain to you.

How Will My Child Feel after the Injections?

All vaccines have some side effects, and your child may experience side effects in this study. The most common side effects of vaccinations are fever, headache, muscle aches or pain, joint aches or pain, tiredness, nausea/vomiting, and chills.

After each injection, your child may have pain or redness and hardness of the skin at the injection site. If the injection was given in the arm, underarm gland swelling may also occur on the arm where the investigational vaccination was given. If the injection was given in the leg, as is commonly done for babies, there may be swelling in the groin.

Most side effects go away within a few days after the injection, and your child should still be able to go about their daily activities. Not everyone has side effects, and these side effects may not be experienced after every dose.

What Are the Risks and Benefits?

There may be no direct benefit to your child from participating in this study. However, information learned from the study may help researchers learn more about vaccines to prevent RSV.

Please ask the study team any questions you have about study participation.

Can I Withdraw My Child from the Study?

You can withdraw your child from the study at any time. Participation is completely voluntary, and you can change your mind about your child's participation. Withdrawing from the study will not affect your child's future medical care.

Thank you for your consideration of the mRNA-1345-P101 RSV Study.

1. healthychildren.org/English/health-issues/conditions/COVID-19/Pages/The-Science-Behind-the-COVID-19-Vaccine-Parent-FAQs.aspx
2. cdc.gov/vaccines/parents/why-vaccinate/vaccine-decision.html
3. health.harvard.edu/blog/why-are-mrna-vaccines-so-exciting-2020121021599

Diseases do not discriminate – and neither should clinical trials.
Moderna is committed to researching safe and effective mRNA-based vaccines and therapies to bring better health and living to people of all ages, sexes, and backgrounds.