

## What is RSV?

RSV, or respiratory syncytial (pronounced sin-sish-(e)-el) virus, is a virus that infects the lungs and breathing passages. Similar to the viruses that cause the flu or the common cold, RSV causes symptoms such as runny nose, cough and trouble breathing, and is extremely common. Almost every infant is exposed to RSV by the age of 2. Many children experience mild symptoms that are mistaken for the common cold and get better without treatment. However, in some cases, especially among newborn babies 0-6 months of age, RSV can develop into more severe complications, such as bronchitis (inflammation of the small airways in the lungs) or pneumonia and may require hospitalization.

## Is there a vaccine to prevent RSV?

No, there is no vaccine to protect against RSV available right now. However, researchers are developing an investigational RSV vaccine that will be given to mothers late in pregnancy to protect their babies from RSV infections. A new study is being done to help determine whether the vaccine given during pregnancy is safe and can protect newborn babies up to 6 months of age from RSV infections.

## What is the study about?

This study is designed to determine whether an RSV vaccine given to pregnant women during the third trimester of pregnancy can protect newborn babies from RSV infection. Similar clinical studies have given investigational vaccines to pregnant women and have been proven to protect newborn babies against tetanus, pertussis (whooping cough) and influenza, leading to licensed vaccines today.

## Who can participate?

To participate in this study, you must be between the ages of 18 and 40 and between 31 and 36 weeks pregnant. You may not participate if you have experienced premature labor, high blood pressure, or pre-eclampsia during your current pregnancy or if you have experienced a prior premature birth or have had more than 5 deliveries.

## What happens during the study?

The study will begin enrolling pregnant women during the three months prior to RSV season. You will receive a single injection of either the investigational RSV vaccine or the placebo (a solution using the same liquid the vaccine is dissolved in, but without the active vaccine components). Neither you nor your doctor will know whether you will be given the active vaccine or the placebo.

To test the effectiveness of the vaccine, blood samples will be taken from both you and your baby. You will receive 5 blood tests over the course of 9 months, and your baby will receive 2-3 blood tests during the first year. Blood draws will be conducted by an experienced phlebotomist. The blood samples will be analyzed to determine whether you and your baby have antibodies against RSV, which could indicate protection against RSV. You and your baby will also be monitored for signs of RSV infection.



## Does it cost anything to participate?

All study exams and procedures are provided free of charge, and you will be reimbursed for your travel costs.

## Why join the study?

Clinical research, like this study, is essential to learn about human health and disease and to provide safe, effective preventative measures. By participating in this study, you may help researchers develop a new vaccine that may protect your baby, and many others, from RSV. Your participation in this research study is completely voluntary.

## Where can I go to learn more?

If you're interested in learning more or in participating in this study, contact:

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