Why should I join this study?

Clinical research, like this study, is essential to learn about human health and disease and to provide safe, effective treatments and prevention measures.

By participating in this study, you may help researchers develop a new vaccine that may protect your baby, and many others, from RSV.

INTERESTED IN LEARNING MORE?

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RSV in Newborns

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.

Researchers are developing an investigational RSV vaccine that will be given to mothers late in pregnancy to protect their babies from RSV infections.

A clinical study is being conducted to help determine whether an investigational RSV vaccine given to a pregnant woman can enable her immune system to provide protection against RSV infection to her newborn baby. This transfer effect between a pregnant woman's immune system and her unborn child's immune systems has been used to protect newborn babies against tetanus, influenza and pertussis (whooping cough).

The possibility of protecting newborns against RSV infection is an exciting vaccine development for several reasons:

- RSV infections occur in nearly all young children
- RSV infections affect children in daycare or at home
- RSV symptoms can be similar to the common cold, but may develop into more severe complications
- RSV most often causes serious illness in infants less than 6 months of age
- There is no vaccine to protect against RSV available right now

Do you qualify?

In order to take part in this clinical trial, you must be between the ages of 18 and 40 and between 31 and 36 weeks gestation. 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.

THE GOAL

The goal of this study is to determine whether an RSV vaccine given to pregnant women during the third trimester of pregnancy can protect newborns babies from RSV infections. 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.

ENROLLMENT

The study will begin enrolling pregnant women during the three months prior to RSV season.

WHAT TO EXPECT

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 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.

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

Your participation in clinical research is completely voluntary.