WHAT ARE THE BENEFITS TO MY BABY?

By participating, your infant will have a 2 in 3 chance of receiving at least one dose of an investigational drug, REGN2222.

- One group of infants will receive 2 doses of REGN2222.
- One group of infants will receive 1 dose of REGN222 and 1 dose of a placebo.
- One group of infants will receive 2 doses of placebo.

If your infant receives REGN2222, they may have some protection from RSV.

WHAT ARE THE SIDE EFFECTS OR RISKS FOR MY INFANT?

Due to the experimental nature of this study, there may be unexpected or unanticipated risks. In similar medications, allergic reactions have been observed which developed either immediately or within a few hours of administration. These reactions, however, have been observed rarely in neonates.

Other side effects that have been documented with similar medications include changes in salivation, antibody production, or injection site reactions. These risks are discussed in more detail in the study consent form.

INFORMED CONSENT

If you are interested in knowing more about the study and qualify, a neonatal research staff member will give you a consent form and describe the study further. They will be able to answer any questions that you may have.

QUESTIONS FOR MY INFANT'S DOCTOR:

_____

_____

_____

_____

_____

AT YOUR CLINIC/MD OFFICE CONTACT:

PI name
PI address
PI phone/fax/email

Regeneron RSV Trial

A double-blind, randomized, placebo-controlled trial evaluating the efficacy and safety of REGN2222, a human monoclonal antibody, for the prevention of medically-attended RSV in preterm infants

WHAT IS THE STUDY ABOUT?

Preterm infants have a higher risk of getting sick from a variety of lung illnesses during the winter months. RSV (respiratory syncytial virus) is one of these illnesses. RSV is a widespread virus that can become a serious respiratory illness in infected infants, especially preterm infants.

Version 2
Approved:
INF-0020

This study is looking at the safety and overall efficacy of the investigational medicine, REGN2222, in preventing RSV-infections that need to be medically treated in a doctor's office, urgent care clinic or hospital.

WHY SHOULD I CONSIDER THIS STUDY FOR MY INFANT?

If REGN222 is shown to be effective and approved by the FDA, it may be used in the future to provide protection to other infants like your son or daughter.

HOW LONG WILL MY INFANT BE IN THIS STUDY?

This study will start when your infant is close to or after discharge from the NICU, ICC or Special Care Nursery.

Your infant will participate in this study for about 8 months. For the first 5 months, you will bring your infant to the hospital for scheduled visits (about once a month). For the final 3 months, research staff will follow up with you by phone (about once a month) to see how your baby is doing.

WHAT WILL BE DONE TO MY INFANT?

If your infant qualifies and you agree to have your infant participate in the study, the following will happen to your infant throughout the course of the study:

- Receive injections into the thigh muscle at two separate time points 8 weeks apart.
- Physical exams
- Three blood sample collections
- Nose swab collection in the event of a suspected RSV infection requiring medical attention
- Additional blood collection in the event of an allergic reaction to the study drug

Following discharge from the hospital, you will be asked to bring your infant back to the hospital for monthly check ups.

If your infant gets sick with a respiratory illness, in between these pre-scheduled monthly checkups you will be asked to bring your infant back to be seen by the study staff for an additional checkup. A nose swab to test for RSV will be collected at these visit(s).

Although unlikely, a reaction to REGN2222 may happen. If your infant develops a reaction, you will need to bring your infant back to be seen by the study staff, all symptoms will be documented and an additional blood sample will be collected from your infant.