

# Evaluation of a New RSV Vaccine for Infants

## What is RSV?

RSV stands for Respiratory Syncytial ("Sin-sish-al") Virus. It is a respiratory virus, meaning that it infects the respiratory tract—ears, nose, throat and lungs.

## Why is it important?

RSV is the most common cause of hospitalization for respiratory illness (illness in the ears, nose, throat or lungs) in babies. It causes:

- Pneumonia
- Bronchiolitis (inflammation of the small airways in the lungs)
- Fever, Runny Nose, Sore Throat, Cough, Ear Infections, Wheezing

## How do people get infected with it?

People get infected when virus from infected people or things that infected people have touched contacts the eyes, nose or mouth.

## How is it prevented?

There is no vaccine for RSV. There is a drug to prevent it, but it is only given to children who have the highest risk for serious RSV disease because they have other health problems. It is not given to healthy children. Good hand washing and avoiding contact with other sick individuals helps people to avoid all respiratory viruses.

## What vaccines are being evaluated?

MEDI-559 is a live RSV virus that has been genetically weakened in the laboratory so that it is not expected to cause significant illness. It is given as nose drops.

## Why is this study being done?

RSV is the most important cause of viral lower respiratory tract illness in infants and children worldwide. The peak of severe disease, and in some cases death from RSV, occurs in infants 2 to 6 months of age. The purpose of this study is to describe the safety, immune response (ability of the body to fight infection), and virus shedding (amount of virus in the nose) in children who receive an investigational live RSV nasal vaccine called MEDI-559 compared to children who receive a placebo (a sugar and salt solution that does not contain the vaccine virus). No vaccine to prevent RSV in healthy children exists, and the goal of this research is to develop one. The information learned in this study may be helpful in the further development of MEDI-559 as a vaccine for the prevention of RSV infections in infants and young children.

## What does the study entail?

If your child qualifies to be in the study, your child will be assigned to **one** of two groups based on your child's age at the time he/she enrolls into the study:

- |                        |                                |
|------------------------|--------------------------------|
| Group 1 (5-11 months): | 3 doses of MEDI-559 or Placebo |
| Group 2 (1-3 months):  | 3 doses of MEDI-559 or Placebo |

MEDI-559 and placebo in this study are given as nose drops. Vaccinations will start with the 5-11 month old children. Children 5 to 11 months old will require a blood collection before being allowed to enter the study to show that he/she has not been previously exposed to RSV virus. If the test shows that your child has previously been exposed to RSV virus, your child will not be allowed to be in the study.

Every child will be scheduled to receive a dose of MEDI-559 or placebo on three separate occasions, each dose separated by approximately 2 months. If your child is 5-11 months old, he/she will have an equal chance (1 in 2, or 50%; like flipping a coin) of receiving MEDI-559 or placebo.

Once 40 children in the 5-11-month old group have received their first dose of study vaccine, enrollment will begin for the 1-3 month olds. This age group does not require a screening blood draw. Every child will be scheduled to receive a dose of MEDI-559 or placebo on three separate occasions, each dose separated by approximately 2 months. If your child is 1-3 months old, he/she will have an equal chance (1 in 2, or 50%; like flipping a coin) of receiving MEDI-559 or placebo.

You will receive a worksheet, a thermometer, and detailed instructions. You will be asked to record your child's temperature and reactions daily for the first 28 days after each vaccine administration.

Follow-up visits to the office are required after each vaccination at 7, 12 and 28 days after each vaccination for a brief examination and a nasal rinse to measure viral shedding.

Additionally, a blood sample (less than 1 teaspoon) will be taken before the first vaccination and 28 days after the third vaccination. These samples will help measure your child's protection level to RSV. These blood samples are done by our nurse in the office. Numbing cream (4% lidocaine) can use used to decrease any discomfort.

### **What are the risks?**

Studies in which MEDI-559-like vaccines have been given to adults, children, and infants suggest that these vaccines have an acceptable safety profile. A study of a vaccine very similar to MEDI-559 in which 32 infants and children received either two doses of a MEDI-559-like vaccine or placebo showed no difference in the occurrence of side effects (such as runny nose, cough, fever, ear infection) between those who received the vaccine or placebo.

MEDI-559 is a live, weakened virus. If the vaccine is not weakened enough, it may cause a fever, cold (runny/stuffy nose, sore throat, cough, fever, feeling tired), or wheezing. More severe illnesses usually associated with naturally occurring viruses, such as ear infections or lung infections (for example, croup, bronchiolitis, or pneumonia) could occur. However, this is not expected from a weakened vaccine virus like MEDI-559. Any respiratory illnesses that occur in your child will be closely examined by the study staff.

### **Why participate?**

RSV is the most important cause of viral lower respiratory tract illness in infants and children worldwide. No vaccine to prevent RSV in healthy children exists, and the goal of this research is to develop one. The information learned in this study may be helpful in the further development of MEDI-559 as a vaccine for the prevention of RSV infections in infants and young children.

When the final blood is drawn in the office for the study, an additional amount can be obtained for a CBC/Lead level, which will be ordered routinely at the 12-month physical. This will save you a trip to a local laboratory for venipuncture.

There is no charge to participate and the vaccines are given free of charge. Your family will be given a \$40 gift card redeemable at a local store at each of the visits for a total of \$480 to \$520 (depending upon your child's age group) to thank you for your time and effort.

**Where can I find more information?** Nancy Wymer RN at 301-662-2051