

Who can take part?

Babies may be eligible for the study if they:

- were born at 35 weeks or later
- have no known history of RSV infection or lung diseases.

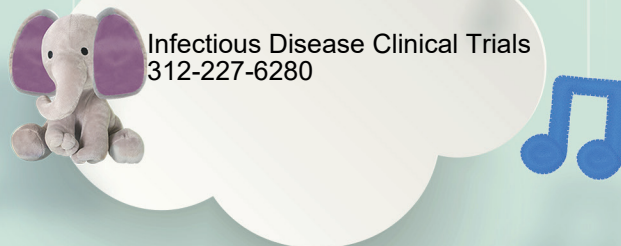
What else do I need to consider?

- You will not be paid for your baby to take part in this study, but you may be compensated for time and travel costs during study participation.
- A team of doctors and nurses will monitor your baby's health carefully during the study.



How do I get more information?

To find out more, contact the study team using the information provided here. By contacting us, you are under no obligation to take part in the study.



**Together let's
find a way
to protect
babies from
RSV infection**

Join this clinical study to research an investigational medicine to prevent lung infections caused by respiratory syncytial virus.

Study Information




What is a clinical research study?

A clinical research study is a medical study that helps to answer important questions about an investigational medication, such as:

- Does it work?
- What amount, or dose, may work best?
- How safe is it?
- Are there side effects?

All medications must be tested in clinical research studies before they can be approved to prescribe to patients. Without people taking part in these important studies, new medications would not be approved by regulatory agencies.



Deciding to take part in a clinical research study is your decision. If you have any questions, you can contact the study team using the information provided in this brochure.

About the MELODY Study

- MELODY is a clinical research study looking at an investigational medication to see how safe it is and whether it works to prevent respiratory syncytial virus (RSV) disease in healthy babies. The investigational medication has been looked at in previous clinical studies for RSV and there were no safety concerns in babies and adults.
- Your baby will be twice as likely to get the investigational medication than placebo (both are called “study medication”).
- A placebo looks the same as the investigational medication but contains no active ingredients. There is no approved therapy to prevent RSV in babies eligible for this study. Therefore, getting placebo will not put your baby at a greater risk for RSV than not participating in the study at all.
- Neither you nor the study doctor will know which study medication your baby will get.

Why is the MELODY Study important?

- RSV is the most common cause of lung infection among babies and young children.
- RSV illnesses in babies can cause serious breathing problems and increase the risk of hospital and doctor visits.
- There are no approved RSV prevention medications for healthy infants and no treatment for active RSV infection. MELODY provides an opportunity to have healthy infants receive preventive medication and to address this unmet medical need.

What will the MELODY Study involve?

If you decide to take part, your baby will be in the MELODY Study for about 1 year and 6 months. The study will include about 3000 babies globally and has 3 periods.

Screening period (up to 30 days)

You will visit the study center with your baby to see if the study is suitable for your baby and whether you want to take part. **This visit could be combined with the treatment period visit.**

Treatment period (about 1 day)

During a visit to the study center, your baby will receive the study medication.

Follow-up period

(about 1 year and 5 months)

During this period, you will have at least 5 study center visits and phone calls. Additional follow-up visits may be needed for respiratory illnesses or skin reactions.