the Journey begins here

The GRACE Clinical Study

A guide to the study and informed consent for parents and caregivers

grace
InvestiGational RSV
mAternal vacCinE study

The GRACE Clinical Study
at a Glance

Thank you for speaking with us about joining this clinical study.

The information we gather in this study may possibly help us develop an RSV maternal vaccine and may benefit children in the future.

Purpose

Doctors and researchers want to learn whether the study vaccine boosts the level of RSV-fighting antibodies in pregnant women and whether these antibodies are passed along to their babies.

Study length

The study will take about 15 to 17 months for you and your baby to complete. For you, the study begins during your second or third trimester and ends about 6 months after your delivery. For your baby, the study begins when he or she is born and ends when he or she is 12 months old.

Enrollment

The study will enroll about 10,000 healthy pregnant women and their babies at clinical sites around the world.

For more information about the potential risks and benefits of participating in this study, please read the informed consent form and speak with your doctor.

What is a clinical study?

In a clinical study, researchers gather information about possible new ways to prevent, diagnose, and treat diseases in people. Researchers may study new vaccines, medicines, devices, and other types of medical treatment.

- The goal of this process is to learn whether these new potential options work well and are safe for people
- That's why clinical studies, sometimes called clinical trials, are important to the future of medicine

What is informed consent?

Informed consent is a process in which the study team gives you information about a clinical study so that you can decide whether or not you want to join it.

- You will be asked to review an informed consent form, which describes the study in detail and its possible risks and benefits for you and your baby
- If you decide that you are interested in joining the study after reviewing this information, the study team will ask you to sign the informed consent form for yourself *and* your baby to participate
- You may decide to end your or your baby's participation in the study at any time, for any reason

Before you decide to join a clinical study, feel free to discuss this information with your doctor and anyone else you would like, including trusted friends and family members.

Your doctor and the study team are your best sources of information about vaccines and clinical studies. **Ask as many questions as you want at any time during the study.**

What is RSV?

- Respiratory syncytial (“sin-sish-uhl”) virus, also called RSV, is a contagious cold-like virus that infects the airways and lungs
- Most cases of RSV cause a simple cold, but in some cases, RSV causes more serious problems with breathing
- RSV infection develops in nearly all children by the time they are 2 years old
- Very young babies, especially those younger than 6 months of age, are more likely to have a severe RSV infection than older children

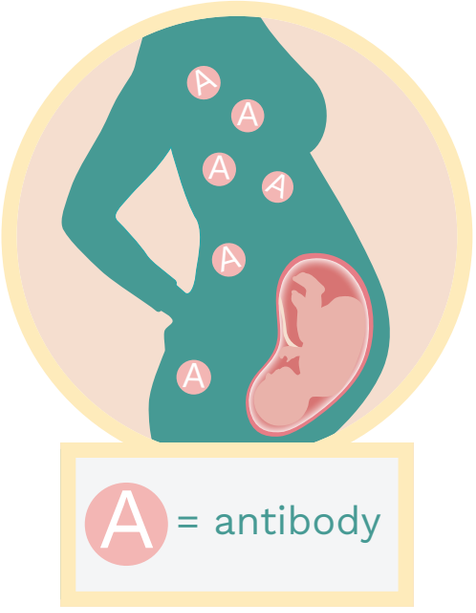
Did you know?

An RSV infection is one of the most common reasons for hospitalisation among babies in the first few months of life.

What is the goal of the study?

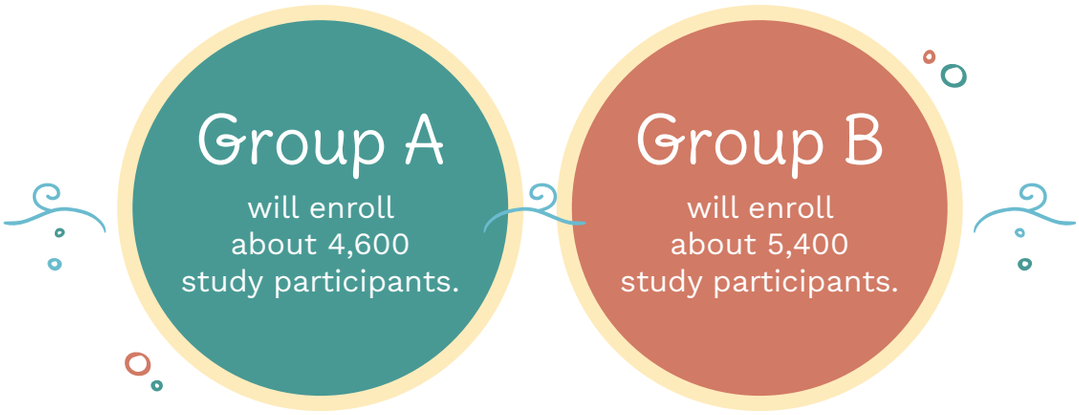
In this study, researchers want to learn

- whether the study vaccine may help boost the level of RSV-fighting antibodies in pregnant women
- whether those antibodies may pass to their babies through the placenta
- more about the safety and potential side effects of the study vaccine for pregnant women and their babies



How is the study being done?

The study is being conducted in 2 groups:



All of the study participants will be randomly assigned (like drawing from a hat) to receive one injection of either the study vaccine or the placebo.

You are twice as likely to receive the study vaccine as you would the placebo; however, you, the researchers, and the study team will not know which injection you are receiving.

No matter which injection you receive, the study team will watch you for any symptoms or side effects for about 30 minutes after you receive the injection.

What is the study vaccine?

- The study vaccine contains an ingredient that is being evaluated to see whether it may help your body create more RSV-fighting antibodies
- The study vaccine is given as a single injection into your upper arm at the first study visit

What is a placebo?

- The placebo is salt water, and it is given in the same way as the study vaccine
- Since a placebo does not contain the study vaccine's active ingredients, researchers are able to see by comparison how much of an effect the study vaccine has on a participant

Please refer to the informed consent form and speak with the study doctor for more information about the potential risks and side effects of receiving the study vaccines.

Do I qualify to take part in the study?

You may qualify to participate in the study if you are*

- a healthy woman aged 18 to 49 years
- in the second or third trimester of pregnancy (between about 24 and 34 weeks of gestation)

The study team will decide whether you qualify for the study during a process called screening.

- At the beginning of the screening visit, you will be asked to sign the informed consent form
- After you provide informed consent, you will undergo different tests and assessments, which may include providing a blood and urine sample for testing. The study will also review your most recent ultrasound scan and may request an additional ultrasound scan for the purpose of screening
- You may be asked to sign another informed consent form when your baby is born

*Additional eligibility criteria apply. Ask the study doctor for more information.

Did you know?

All vaccines are tested in clinical studies before they are considered for approval and then recommended for use in people.

What is expected of me and my baby if we participate?

For you

About 4 scheduled study visits beginning in your second or third trimester of pregnancy and concluding when your baby is 6 months old.

For your baby

About 5 scheduled study visits beginning at birth and concluding when your baby is 12 months old.

Additional study visits may be required if you or your baby develops cold-like symptoms, including

runny or blocked nose

coughing

difficulty breathing, or wheezing

- If you notice any cold-like symptoms within 6 months of giving birth, you should contact your study team immediately
- For about 9 months after your baby is born, the study team will contact you regularly to ask about his or her health. Contact the study team immediately if you notice cold-like symptoms or other changes in your baby's health

Your Study Visit Schedule

Screening	Visit 1	Visit 2	Visit 3	Visit 4
				
Before you can be in the study	**You are 24-34 weeks pregnant**	**About 30 days after Visit 1**	**Baby's birth**	**6 weeks after delivery**
			Baby's Visit 1	**Baby's Visit 2**
• Before you can receive the study vaccine or placebo, discuss the study with the study team, ask any questions and sign the informed consent form • Medical history • Physical exam	• Receive the study vaccine or placebo* • Blood draw • Physical exam • Review of medicines and symptoms	• Blood draw • Physical exam • Review of medicines and symptoms	• Umbilical cord blood sample† • Blood draw (group A subgroup only) • Physical exam • Give informed consent for your baby or confirm consent for you, if required by your country • Review of medicines and symptoms	• Physical exam • Review of medicines and symptoms

To see how you are feeling, the study team will contact you about **once a month** until you give birth and then at **6 months** afterward.

*Followed by a 30-minute observation period. If you are in group A, you will be asked to record any side effects in a diary for 7 days after receiving the study vaccine.
†Collection of a cord blood sample does not interfere with cord blood banking.

Your Baby's Study Visit Schedule

Visit 1	Visit 2	Visit 3	Visit 4	Visit 5
 **Baby's birth**	 **Baby is 6 weeks old**	 **Baby is 4 months old**	 **Baby is 6 months old**	 **Baby is 12 months old**
Your Visit 3	**Your Visit 4**			
• Physical exam • Blood draw, only if cord blood was not collected • Review of medicines and symptoms	Blood sample (taken randomly at **one** of these three visits only if you are in the group A subgroup)			• Physical exam • Review of medicines and symptoms
	• Physical exam • Review of medicines and symptoms	• Physical exam • Review of medicines and symptoms	• Physical exam • Review of medicines and symptoms	

To see how your baby is feeling, the study team will contact you about **once a month** or more often if needed.

Notes

Understanding
the Key Activities and Assessments of the Study

These are a few of the activities and assessments that may be performed while you and your baby are in the study.

If you have any questions or concerns about these assessments or anything else **at any time** during the study, ask the study team.

Medical history. At the first visit, the study team will ask you questions about any previous vaccinations, medicines, or illnesses you have had.

Blood draws. Blood samples may be taken from you and your baby at different times throughout the study. Testing blood samples helps the study team see whether your body is responding to the study vaccine. The cord blood sample is tested to see whether any RSV antibodies have passed to your baby.

Physical exam. For you and your baby, a physical exam may include recording height, weight, body temperature, blood pressure, heart rate, breathing rate, and blood oxygen level. You will also have obstetric exams.

Review of medicines and symptoms. The study team will ask you at every visit whether there have been any changes to the medicines or vaccines that you or you baby receive* and whether you have noticed any symptoms or changes in your or your baby's health.

Nose swabs. If you or your baby has a visit for cold-like symptoms, such as a cough or runny nose, the study team will use a soft-tipped swab to collect liquid from your or your baby's nose to see whether those symptoms are caused by RSV.

*The study team will tell you which medicines you can and cannot take during the study.

My Study Documents

Contact us with any questions you may have:

.....

STUDY DOCTOR

.....

STUDY COORDINATOR

.....

PHONE NUMBER

Thank You for Your Interest!

Talk with us. We can give you and your family more information about the study.

Together, we can learn more about the potential to help prevent RSV disease among babies.

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