

Can I change my mind about having my baby in this study?

Having your baby take part in the HARMONIE Study is your choice. If you agree for your baby to take part, you can change your mind and leave the study at any time. This will not affect your baby's regular medical care.

Will I receive any payments for taking part in the study?

While we are not offering payment to parents who enroll their children, we will be able to compensate you for the e-Diary completion. The study team will be able to tell you more about this at the first appointment.

Are there any benefits or risks?

There is no guarantee of any medical benefit from participating in this study. If your baby receives the antibody dose, there is a chance this will reduce the risk of RSV infection.

As with any medications, there may be some side effects associated with dosing. Previous trials have shown good safety results with most side effects relating to the injection itself, for example a sore leg. The study doctor or study staff can talk these through with you.

Will my baby's privacy be protected?

The study Sponsor and its partners involved in the study will not know who your baby is; they will receive all the data collected during the study only after the data have been anonymised. This is done to protect your baby's privacy and your privacy.

How do I find out more information about the HARMONIE Study?

On the study website you can find further information about the HARMONIE Study, and you can answer a few questions to find out if your baby may be able to take part.

Please visit RSVHarmonieStudy.com.

Thank you for taking the time to find out about the HARMONIE Study.



RSVHarmonieStudy.com

Help us protect babies from respiratory infections in the future



All babies may benefit from protection from RSV – a virus that can cause respiratory infection.



Introduction

You are invited to consider agreeing to be contacted by a research team to receive information about the HARMONIE Study that aims to prevent respiratory infection in babies commonly caused by the respiratory syncytial virus (RSV).

The HARMONIE Research Study follows on from other research studies which have been completed and is looking at how strongly babies can be protected from serious illness due to RSV infection by giving them a single antibody dose. More than 3000 babies have already been given this antibody dose and were monitored closely in clinical trials. These trials have shown that this antibody dose has been well tolerated and has shown good safety results.

More information and a summary of the study are included below. Thank you for taking the time to consider the HARMONIE Study for your baby.

What is RSV and why should I be aware of it?

RSV is a common seasonal virus that infects nearly all babies by their second birthday. Most of the time it causes a mild illness, like a cold. However, for some babies, it leads to more severe lung problems such as bronchiolitis and pneumonia.



Who will take part in this study?

As many as 28,860 babies in the UK, France, and Germany will take part in the HARMONIE Study. This study will include newborn babies to babies 12 months old who are in, or are approaching, their first RSV season. The study doctor will confirm if your baby can take part in the study based on your baby's medical records.

If we take part in the HARMONIE Study, will my baby get the antibody dose?

If the study is appropriate for your baby, they will be randomly assigned into one of two groups. One group will receive the antibody dose by having an injection into their thigh, in the same way your baby will receive their routine vaccination injections, and in the other group no injection will be given. Putting the babies into two groups in this way ensures there is no bias as to which group the babies are assigned.

If assigned to the group that receives the antibody dose, your baby won't have any tests, injections, or examinations after this as part of the study.

If your baby is not assigned to get the antibody dose, then you will still be a very valuable part of this research and how protection from RSV is managed in the future and your baby will be followed up in the same way.

How long is this study?

The HARMONIE Study will last about 12 months for you and your baby, and participation involves the following:

- 1 visit to the study site - This is called the study visit and is when the antibody dose would be given.
- Monthly diary for 6 months - You will be asked to answer a short selection of yes/no questions once a month for a 6-month period. This can be done from the comfort of your home.
- 1 telephone call with the study team 12 months after the study visit

These follow-up activities are for parents of all babies who take part in the study. Even if your baby does not receive the antibody dose, the information you provide will be extremely useful and vital to the success of the study.



Why is RSV protection important for all babies?

RSV infection is unpredictable and is a leading cause of hospitalisations in babies. Most hospitalisations due to RSV occur in otherwise healthy babies, and it is difficult to know which babies will develop severe disease requiring medical care.

What do we know about this antibody dose?

Antibodies are found in the blood and are part of our immune system, which helps our bodies fight infection and illness. The antibody dose in the HARMONIE Study acts in the same way as the antibodies within our own bodies, but it is targeted specifically to fight RSV.

This preventative solution is the result of many years of research by Sanofi and AstraZeneca and has already been given to more than 3000 babies. Several studies have been completed and have shown this antibody dose to work well. The antibody provides direct protection against RSV in one dose. The objective of the HARMONIE Study is to further assess the impact on hospitalisations due to RSV with more babies involved.