HARMONIE STUDY

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.

The HARMONIE Research Study is looking at how strongly babies can be protected from serious illness due to RSV infection (respiratory syncytial virus) by giving them a single antibody dose.

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 the HARMONIE Study?

This study will include as many as 28,860 babies, from newborns to babies 12 months old, in the UK, France, and Germany.

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. For the babies not receiving the antibody dose, the information you will provide will be extremely useful and vital to the success of the study. 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.

How long is the HARMONIE Study?

The 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

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