

Dear Parent/Carer,

We are inviting you and your child to consider joining a clinical study that may protect your child from Respiratory Syncytial Virus (RSV) infection and acquiring RSV-related disease.



What is a clinical study?

A clinical study involves research using human volunteers (also called participants). The goal is to add to existing medical knowledge and available information about an investigational treatment, which could be a medicine or a vaccine.



How is this study being done?

This study is assessing an investigational nasal spray vaccine in children 6 to 22 months of age in several countries. The study lasts 24 months. There will be 2 administrations of either the study vaccine or a placebo, given about 2 months apart. The placebo does not contain any active ingredients. The study vaccine and placebo are both administered into the nose using a nasal spray device.



Why is a vaccine for RSV needed?

RSV is a common seasonal virus and infects almost all children by their second birthday. Most of the time, it causes a mild illness, like a cold. However, for some children it leads to more severe lung problems, such as bronchiolitis (an infection of small airways in the lung called bronchioles) and pneumonia, which may lead to admission to hospital.



Is the study vaccine safe and effective?

The vaccine has been tested in humans before, and other RSV vaccines very similar to this one have also been tested in both adults and children. There were not many side effects, and there was an immune response.



If we join the study, will my child be protected from RSV?

Your child has a 50% chance of getting the active study vaccine or a placebo, which has no active ingredients. The study vaccine is still under investigation. This means that we cannot guarantee that your child will be protected from RSV by participating in the study.

The study vaccine and study-related procedures are provided at no cost to you. You will not be paid for being in the study, but reimbursement for expenses may be available according to local law.

Being in this study is 100% up to you and your child. Please keep in mind that even if you decide to participate, the study doctor will need to verify that your child can take part in the study.

If you are interested in learning more, please contact the study staff:

