

STOP RSV

Surveillance towards Preventing RSV Respiratory Infection in Children

'Coughs and Sneezes Study'

Young children with symptoms of a cough, cold or chest infection under 3 years of age are invited to take part in this research



(new-born to under 3 years age)

Why is this study needed?

Chest infections such as bronchiolitis can occur when a common cough or cold virus moves from the nose to the lungs leading to difficulty breathing. Often this is caused by the Respiratory Syncytial Virus (RSV). Young children have smaller airways and less immunity so are at more risk. Each year as many as 4 in 100 (4%) children under 3 years age are admitted to hospital.

This study aims to find out more about:

- respiratory infections caused by this virus
- what impact this illness has for children, families and health care.

Which children may take part?

- Children under 3 years of age who attend a hospital, a GP Practice or Walk-in Centre (or consult by telephone) with cough, cold or chest infection symptoms.

We aim to recruit 1800 children to take part in this research.

Before you choose whether to take part

Please read the following and ask us if you would like more information.

Does my child have to take part?

No. Taking part in this study is voluntary. If you choose not to take part this will not in any way affect the care you receive in the NHS.

What will happen if I agree for my child to take part? We will ask you:

- to sign a consent form
- to answer a few questions about your child's health and symptoms
- if we may collect secretions from your child's nose with a swab and for some children a nasal strip (*see below*).
- to complete two short questionnaires in the next month.

Nose swabs and strips:

We will ask if we may swab your child's nose for this research. Some children may require a swab as part of their standard NHS care taken by the clinical team or a COVID -19 test. Rather than asking for an additional research swab we would ask you if we may contact the laboratory to use the swab already taken for this research.

We will ask some parents if we may also place a nasal strip in their child's nose for about 10 – 30 seconds to collect nasal liquid.



Photo with a pound coin to compare the size

Nasal Strip (*similar to thick paper*)

Nasal Swab (*similar to a cotton bud*)

If your child is unsettled, we will wait for a time that you feel that is better for them to have a swab.

Short Questionnaires (*take about 10 minutes each*). We will ask you to complete this after two and four weeks.

You may choose to complete this either online, by post or a telephone call with the research nurse or data manager.

The questionnaires will ask how long your child's symptoms lasted, what health care they needed, any effect on your child being unable to attend nursery/day care or if you needed to take time off to provide care for your child at home or in hospital. We will also collect data on their medical history and health care.

Can my child take part if my GP assess my child over the phone? Yes, you may choose to have a swab posted to your home (we pay return postage). If you do collect a swab at home, we would like you to return it as soon as possible, ideally the same day you receive it.

Or if your GP asks you to attend the practice to be assessed for the research, we will pay travel expenses (*we will ask for receipts or confirm mileage up to a maximum of £30*).

What are the benefits of the study and for my child if they take part?

There will be no direct benefits to your child by taking part.

This study will provide information about the number of children with RSV infection, the burden to families and health care. These data may support the need for preventive therapies when they become available in future. Vaccines and other preventive therapies to protect against this illness are not routinely available for all young children. In this observational study we will not offer your child any preventive therapy.

Are there any disadvantages to my child taking part in this study?

We expect very mild discomfort from the swab or filter strip.

Will my child's GP be informed of their participation in this study?

The GP or hospital doctor that requests the swab for this research will be informed of the viral swab results and will inform you if there is any change to your child's care. Otherwise, if you choose to you may contact the

research nurse at the time of two week questionnaire to request the result.

What will happen to the samples? After testing in the NHS laboratories, the samples may be transferred (without any personal details) to Liverpool School of Tropical Medicine. With your permission we may then share samples with other research institutes for relevant research.

Will the information on my child be kept confidential if I choose to participate?

Your child's personal information will be kept secure and confidential (as required by the Data Protection Act 2018 and UK-GDPR). If you choose to consent the clinical team at the NHS sites, LSTM clinical research team may access your contact details and your child's personal and medical information relevant to this research. The researcher will use a code to anonymise your child's personal identifiable data before transfer to LSTM so that these data can not be traced back to you or your child. Data are kept for at least five years in a password protected system. Information on privacy is available on www.lstmed.ac.uk/lstm-privacy-statement or www.hra.nhs.uk/information-about-patients/.

What will happen to the results of the research study?

The results will be published in medical journals and a summary on the web site of the Liverpool School of Tropical Medicine (LSTM).

What if you have a concern or complaint to make about the study?

You can contact the research team at Liverpool School of Tropical Medicine who sponsor this study. If at any time you change your mind you may withdraw from the study without giving a reason. Tel:

The study is funded by SANOFI and approved by the NHS Research Ethics Committee.

If you would like further information, please contact:

Local Contact details
Web site