

Preschool Wheeze: Predicting Progression to School Aged Asthma.

Information sheet for parents

Your child has been invited to take part in a research study. Before you decide if you are happy for him/her to take part you need to understand why the research is being done and what it would involve for your child. Please take time to read the following information carefully. Talk to others including your family, friends, doctor or nurse about the study if you wish.

If anything is not clear and you require more information before you decide whether or not your child should take part in the study please speak to one of the study team.

Thank you for taking the time to consider your child taking part in our study.

Information about the research

Why is this study being done?

Asthma and pre-school wheeze are common conditions, caused by inflammation in the lungs. When severe, it can result in missing school and admissions to hospital. We are doing this research project in order to understand how the type of inflammation and infection in the airways (breathing tubes) of children in preschool years impacts the health of their lungs later in childhood and whether they develop asthma.

Your child had been part of the first part of this study as a pre-schooler when they had their bronchoscopy (camera test) at the Royal Brompton Hospital. The information that we gained from this study was very interesting and showed there are differences in the types of bacteria and patterns of infection and inflammation in children with severe wheeze.

We are doing this follow-up study now so that we can see if those patterns of infection and inflammation will predict outcomes at school age. This could mean that more specific possible treatment options could one day be identified for children with preschool wheeze.

Why has my child been chosen?

Your child has been chosen because you had kindly consented to their participation in when they were a pre-schooler, part of study that was called "Patterns of Infection and Inflammation in Children". They may have had severe wheeze as a pre-schooler or they were undergoing bronchoscopy for other respiratory

symptoms such as chest infections or cough. There were just over 130 participants, including your child, in the original study. We have written to each of these families to ask if they would kindly participate in this follow-up and we hope to see as many of them again as possible.

What will happen if I do not agree to my child taking part?

Your child's normal treatment will not be affected in any way if you do not take part. They will still continue to receive the best possible care from the NHS at all times. Your child's participation is also entirely voluntary. They can say no to taking part or change their mind at any point.

What will happen if my child takes part?

If you agree to take part, a member of the clinical research team will meet you and your child during a research visit at the Royal Brompton Hospital for an interview about their breathing symptoms. This should take around 15 minutes and involves asking some brief questions about their symptoms, medical and family history, any medication that they use and a short questionnaire about asthma. We would then like your child to do some tests that will help us see the health of their lungs and look for current infection and inflammation in their airways.

If you agree, we will inform your child's GP that they are part of this study and let them know any important results of tests relevant to your child's health. We will also ask your child's GP for information specifically about any asthma medications that have been prescribed for them and any recent wheezing or asthma attacks.

What tests will my child have?

1. We would like to check your child's lung function, (blowing tests) to assess the way in which their lungs are working. This is done by breathing into a machine and we have three different tests:
 - They will be asked to breath normally into a machine for 2 minutes whilst you or one of our research team gently supports their cheeks, this is called a forced oscillation technique.
 - They will be asked to breathe in and out normally for about 2 minutes into another machine, this is called a multiple breath washout test.
 - They will be asked to breath out as hard as possible into and a machine before and after being given a Salbutamol (an inhaler than relaxes the muscles of the airways), this is called spirometry with bronchodilator reversibility.

Sometimes doing lung function tests can make your child feel momentarily short of breath or lightheaded or feeling that their heart is racing. This resolves when they stop the tests and so we will regularly check how they are feeling and ask them to pause if needed.

2. We would like to check the inflammation in the breathing tubes indirectly using a test called exhaled nitric oxide. This is another blowing test which involves blowing out into a machine for up to 10 seconds.
3. We would like to take a swab from their nose and throat to check for infection. The swabs have a soft tip and aren't painful but can feel a little uncomfortable and make them cough.
4. We will collect a sample of the fluid lining the nose from inside the nostril using soft, absorptive filter paper (a bit like blotting paper) placed in the nostril and removed after about 30 seconds. This is a new way to look for inflammation which does not hurt but the nose clip might feel a little uncomfortable.
5. We would like to do a skin-prick test for respiratory allergies. This involves a small amount of liquid containing traces of known common allergens being placed on your child's forearm and a tiny 'prick' being made at the surface of the skin for each liquid. We can typically test 6-8 allergens at a time. An allergic response will result in a reddened, raised area of skin at the site of the liquid allergen. This test is not painful but if there is a reaction the skin can become red and itchy. If the reaction is significant we can give your child an antihistamine cream afterwards.
6. We would like to collect a blood sample to check for allergies, vitamin D level and markers of inflammation. This will be approximately a teaspoon's amount of blood (5mls) and your child can have a local anaesthetic cream or spray applied so that the test is not painful. Very rarely your child might develop a tiny bruise at the site of the blood test that should heal quickly.
7. We would like to save a small amount of your child's blood sample as DNA storage that could be analysed for genes specifically related to asthma in the future. This will help future researchers understand the role of genes and DNA in the development of asthma. We will not be testing for other genetic conditions and will not contact you or your child in the future about these results.
8. We also would like to collect a sample of sputum (phlegm). After inhaling a salty mist (nebuliser) your child will be asked to cough and the sample will be collected. The salty mist can cause some irritation and nausea. It can also, very occasionally, lead to a worsening of asthma and make their chest feel tight. We will give them some treatment (salbutamol inhaler) prior to the procedure to prevent this happening and can give more again afterwards if needed. To make this test as safe as possible, we will adjust the concentration of the salty nebuliser based on your child's lung function result to avoid side effects of chest tightness. We will use the sample to look for infection and inflammation.
9. We would like to collect a urine sample that will be used to look for passive smoke exposure and will be analysed for signs of inflammation.

Your child may agree to do some of the tests and not others and can change their mind about or stop a test at any point.

How long will the study last?

The tests and questionnaires will be completed in one visit at the Royal Brompton Hospital. We do not anticipate needing to ask you to return for a second visit as part of this specific study.

What are the possible disadvantages or risks of my child taking part?

In order to participate in the study, you will be asked to come to the Royal Brompton Hospital research facility, based in our out-patient department. This means making a journey that you would not otherwise have needed to and so we will offer reimbursement for your travel costs. If your child is already a patient at the Royal Brompton Hospital and you would prefer to have the research visit on the same day as their next appointment, please let us know and we will try to arrange this.

The tests that we will ask your child to do can take a few hours in total to complete so you may be with us for half a day, although each child is of course different and may take slightly longer or be slightly quicker. You and your child will be offered light refreshments of snacks and drinks.

All of the above-mentioned tests have been used before in our centre and many are performed routinely for infants, children and adults at our unit. They have been found to be safe and without significant risks but your child might find some of the tests uncomfortable. We will make every effort to minimise any discomfort and have an experienced team of specialists who are specifically trained in doing each particular test in children in a child-friendly and supportive environment. You or your child can of course stop a test at any stage.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If your child experiences harm or injury as a result of taking part in this study, you will be eligible to claim compensation on their behalf without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation. If your child is harmed due to someone's negligence, then you may have grounds for legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you or your child have been treated during the course of this study then you should immediately inform the Investigator Dr Louise Fleming.

The normal National Health Service mechanisms are also available to you, via the Patient Advice and Liaison Service (PALS) Tel: 0207 352 8121 Extension 2803, Email: pals@rbht.nhs.uk If you are still not satisfied with the response, you may contact Imperial College, Research Governance and Integrity team.

What are the advantages of my child taking part?

You will be able helping us to try to work out how best to treat children with wheezing and breathing problems in the future! Also, your child will be having test that they may not otherwise have available to them and will receive a thorough assessment of how their lungs are working and their allergy status. Many of the results will be fed back to you on the same day.

Sometimes when we have analysed the results of these tests, we may also identify something that needs further treatment or investigation that might otherwise have been undetected. We may also be able to recommend whether or not your child would benefit from being formally referred to our respiratory service for follow-up as a patient. In this situation we will contact you to let you know and inform your GP or hospital team, if you agree.

For example, your child is having allergy testing and both you and your child's GP / hospital doctor will be informed if any allergies are found. Similarly, if there is any infection found, your child's GP / hospital doctor will be informed and your child will be offered antibiotics to treat it as appropriate. If your child's breathing and inflammation tests show evidence of inflammation that needs further treatment such as with an inhaler, again you child's GP/ hospital doctor will be informed so that appropriate medication can be started for your child to better manage their symptoms.

As a token of gratitude for their time, each participant attending for a research visit will be offered a £10 amazon voucher.

Can I stop my child from being part of the study even if I initially agree?

Yes. You can decide to withdraw from the study at any time. This will not affect your child's treatment in any way. If you do decide to stop taking part in the study, we will ask whether you will allow us to use the information collected until that point in the study, but if you do not want anything relating to your child to be included, we will destroy all information and samples collected.

If at any point during the study, the parent/guardian who has given informed consent for their child's participation then losses capacity to consent, their child will be withdrawn from the study. Any identifiable data or tissue already collected with consent will be retained and used for the study but no further data collection or procedures would be undertaken.

Will my child's details and information be confidential?

Yes. All of your child's personal details will be kept anonymised and confidential. Any results from the study will not allow your child to be identified in any way.

What will happen to the samples taken during the study?

We will use the samples taken to determine inflammation and infection. If there are any surplus samples remaining, we will ask you if they can be stored confidentially for future tests that are done as part of this study, or another ethically approved study. But, if you do not want any surplus samples to be stored, we will destroy them.

What happens when the research study stops?

This study will only be looking at the health of your child's lungs at one visit and so when the study stops, there will be no change in the follow-up arrangements you may already have with your hospital team, GP or any other part of the NHS. Your child's treatments and medication will continue as normal and as recommended by your child's own doctor and any important findings from the study will be communicated to you.

What will happen to the results of the study?

The results will be presented at national and international medical conferences. They will also be published in a medical journal so that other doctors worldwide can learn from this study. We will use appropriate patient facing social media and channels via Imperial College Public Relations team to share the key results of this study so that patients can learn from our research too. If you would like a copy of the eventual publication, just let us know and we can arrange this to be sent to you directly.

This study and the results will also be part of an MD(res), registered as a post graduate research degree at Imperial College London.

Who is organising and funding the study?

The study is being organised at The Royal Brompton Hospital and Imperial College London is the sponsor. The study is being funded by Action Medical Research. The main person in charge of the study is Dr Louise Fleming.

No individual researchers will receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research.

Who has reviewed the study?

This study was given a favourable ethical opinion for conduct in the NHS by London Harrow REC (ref 21/PR/0422).

Contact details for more information

Research Nurse: 0207 352 8121 ext 88233

Research Clinical Fellow: 0207 352 8121 ext 88257

Website for information on public involvement in research at the Royal Brompton Hospital:
www.rbht.nhs.uk/research/public-involvement-our-research

Data Handling and GDPR

How will we use information about your child?

Imperial College London is the sponsor for this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Imperial College London will keep your child's personal data for:

- 10 years after the study has finished in relation to data subject consent forms.
- 10 years after the study has completed in relation to primary research data.

We will need to use information from your child including their hospital medical records and GP prescription records for this research project. This information will include: hospital number, name, your contact details. People will use this information to do the research or to check your child's records to make sure that the research is being done properly.

People who do not need to know who your child is will not be able to see their name or contact details. Their data will have a code number instead. We will keep all information about your child safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that your child took part in the study.

Legal basis

As a university we use personally-identifiable information to conduct research to improve health, care and services. As a publicly-funded organisation, we have to ensure that it is in the public interest when we use personally-identifiable information from people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use your data in the ways needed to conduct and analyse the research study.

Health and care research should serve the public interest, which means that we have to demonstrate that our research serves the interests of society as a whole. We do this by following the [UK Policy Framework for Health and Social Care Research](#)

International transfers

There may be a requirement to transfer information to countries outside the European Economic Area (for example, to a research partner). Where this information contains your personal data, Imperial College London will ensure that it is transferred in accordance with data protection legislation. If the data is transferred to a country which is not subject to a European Commission (EC) adequacy decision in respect of its data protection standards, Imperial College London will enter into a data sharing agreement with the recipient organisation that incorporates EC approved standard contractual clauses that safeguard how your personal data is processed.

Sharing your information with others

The Trust will keep your child's name and contact details confidential and will not pass this information to Imperial College London. For the purposes referred to in this privacy notice and relying on the bases for processing as set out above, we will share your personal data with certain third parties.

- Other College employees, agents, contractors and service providers (for example, suppliers of printing and mailing services, email communication services or web services, or suppliers who help us carry out any of the activities described above). Our third party service providers are required to enter into data processing agreements with us. We only permit them to process your personal data for specified purposes and in accordance with our policies.

What are your choices about how your information is used?

You can stop your child being part of the study at any time, without giving a reason, but we will keep information about them that we already have.

- We need to manage your child's records in specific ways for the research to be reliable. This means that we won't be able to let you or your child see or change the data we hold about them.
- If you agree for your child to take part in this study, they will have the option to take part in future research using their data already saved from this study. This may include bodily fluid samples that are stored at the Royal Brompton Hospital Biobank.

Where can you find out more about how your information is used

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by email to Imperial College London's Data Protection Officer dpo@imperial.ac.uk
- by telephone on 020 7594 3502
- by post at Imperial College London, Data Protection Officer, Faculty Building Level 4, London SW7 2AZ