Imperial College London

Preschool Wheeze: Predicting Progression to School Aged Asthma.

Information sheet for participants, age 16-18years

You have been invited to take part in a research study. Before you decide if you are happy for to take part you need to understand why the research is being done and what it would involves. 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 you should take part in the study please speak to one of the study team.

Thank you for taking the time to consider 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.

You had been part of the first part of this study as a pre-schooler when you had a 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 have I been chosen?

You have been chosen because your parent/guardian had kindly consented to your participation when you were a pre-schooler, part of study that was called “Patterns of Infection and Inflammation in Children”. You may have had severe wheeze as a pre-schooler or were undergoing bronchoscopy for other respiratory

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

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

Your normal treatment will not be affected in any way if you do not take part. You will still continue to receive the best possible care from the NHS at all times.

What will happen if I take part?

If you agree to take part, a member of the clinical research team will meet you during your research visit at the Royal Brompton Hospital to ask you about your breathing symptoms. This is called a research interview and takes around 15 minutes and involves asking some brief questions about your breathing, medical and family history, any medication that you use and a brief questionnaire about asthma. We would then like you to do some tests that will help us see the health of your lungs and look for current infection and inflammation in your airways. You can choose whether or not to have a parent with you for any part of the research visit.

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

What tests will I have?

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

   Sometimes doing lung function tests can make you feel momentarily short of breath or lightheaded or as if your heart is racing. It resolves when you stop the test and so we will regularly check how you are feeling and if this happens ask you to pause the test until you feel better.
2. We would like to check the inflammation in your breathing tubes indirectly using a test called exhaled nitric oxide. This is another blowing test which is involves blowing out into a machine for up to 10 seconds.

3. We will take a swab from your nose and throat to check for infection. The swabs have a soft tip and aren't painful but can feel a little uncomfortable or make you cough.
4. We will collect a sample of the fluid lining the nose from inside your 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 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 be come red and itchy. If the reaction is significant we can give you 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 you can have a local anaesthetic cream or spray applied so that the test is not painful. Very rarely you might have a tiny bruise at the site of your blood test that should heal quickly.
7. We would like to save a small amount of the blood as DNA storage that could be analysed for genetics 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 family in the future about these results.
8. We also would like to collect a sample of sputum (phlegm). After inhaling a salty mist (nebuliser), you 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 your chest feel tight. We will give you some treatment (salbutamol inhaler) prior to the procedure to prevent this happening and can give you 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 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 may agree to do some of the tests and not others and can have a break, change your 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 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 you are already a patient at the Royal Brompton Hospital and would prefer to have your research visit on the same day as you next appointment, please let us know and we can try to arrange this for you.

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

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 you might find some of the tests uncomfortable. We will make every effort to minimise any discomfort and have an experience team of specialists who are specifically trained in doing each particular test in young people in a supportive environment.

What if something goes wrong?

Imperial College London holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you will be eligible to claim compensation without having to prove that Imperial College is at fault. This does not affect your legal rights to seek compensation. If you are 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 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 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 will be having test that you may not otherwise have available to you and will receive a thorough assessment of how your lungs are working and your 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 you 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, you are having allergy testing and both you and your GP / hospital doctor will be informed if any allergies are found. Similarly, if there is any infection found, your GP / hospital doctor will be informed and you will be offered antibiotics to treat it as appropriate. If your breathing and inflammation tests show evidence of inflammation that needs further treatment such as with an inhaler, again your GP/ hospital doctor will be informed so that appropriate medication can be started for you to better manage your symptoms.

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

Can I stop 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 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 you to be included, we will destroy all information collected.

If at any point during the study, you then lose capacity to consent, you 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 details and information be confidential?

Yes. All of your personal details will be kept anonymised and confidential. Any results from the study will not allow you 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.

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What happens when the research study stops?

This study will only be looking at the health of your 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 treatments and medication will continue as normal and as recommended by your 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 xxxx REC.

Contact details for more information

Research Nurse: xxx ext xxx

Research Clinical Fellow: xxx ext xxx

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 you?

Imperial College London

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 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 you including 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 records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see you name or contact details. Your data will have a code number instead. We will keep all information about you 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 you 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 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 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 records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data 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.