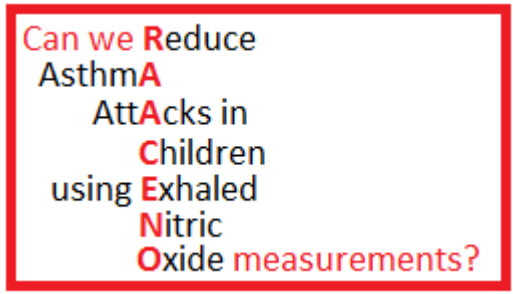
Can we Reduce Asthma Attacks in Children using Exhaled Nitric Oxide measurements? (RAACENO)



We would like to invite your child to participate in a research study which will test whether a breathing test every three months can help prevent asthma attacks. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read this information carefully and to discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish your child to take part.

Thank you for reading this.

What is the purpose of the research?

We all have a gas called nitric oxide in the air we breathe out. People of all ages with asthma have more nitric oxide in their breath than people without asthma. Nitric oxide levels go up before and during an asthma attack and come back down after an attack. The reason for the link between nitric oxide and asthma is that the same part of the body's immune system which causes allergy and asthma (cells called eosinophils) also produces nitric oxide.

Usually at an asthma check-up the doctor or nurse asks how your child's asthma has been, about any coughing or wheezing, and how often they use their blue inhaler. The doctor or nurse uses this information to help decide whether the asthma inhalers and any other medicines that your child takes should stay the same or be changed.

We are doing this study to see whether measuring the levels of exhaled (breathed out) nitric oxide at an asthma check-up would help a doctor or nurse to make these decisions about children's asthma treatment.

In this study, one group of children who take part will have their asthma managed in the normal way (the doctor or nurse will ask about their asthma and how often they use their inhaler), and one group will be managed in the normal way plus have their exhaled nitric oxide results used. We will collect information about any asthma attacks from all the children who take part. We will then compare whether one group has fewer asthma attacks than the other group.

To do this study properly we need 502 children with asthma from up and down the UK.

Why has my child been chosen?

We have approached you about this study because your family doctor thinks that the study may be right for your child. This is because your child has asthma, has had an asthma attack in the last year so may be at risk for another attack, and is between ages 6 and 15 (where we know the nitric oxide test can be done).

Do we have to take part?

No, it is up to you to decide whether or not your child can take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care your child receives.

What happens if my child participates?

If you take part in the study we would like you and your child to come to your local general practice every three months for a year.

The first visit will last up to 90 minutes. During this time we will ask you and your child about your child's asthma. We will also ask you to fill in a questionnaire which tells us about your child's asthma and their recent symptoms. We will measure your child's height, weight and lung function (just like a regular

asthma clinic). We will also measure your child's breathed out nitric oxide by asking them to breathe out slowly into a small machine for six to ten seconds (see photos on below). You can also see videos of these tests being done at www.raaceno.co.uk.

Here is a photo of a young girl blowing into the nitric oxide machine….

….and here is a photo of the nitric oxide machine

NIOX VERO®

At the end of your first visit your child will be randomly placed in a group. Either they will be in the group where asthma treatment depends on asthma symptoms alone OR they will be placed in a group where asthma treatment depends on asthma symptoms plus levels of exhaled nitric oxide.

Regardless of which group your child is in, their asthma treatment may stay the same or be changed slightly. There will be no big changes to your child's asthma treatment. Just like a normal asthma check up, at the end of the visit you will get a prescription to go to your chemist for any changes to your child's medication. We will write to your child's GP with all the details of the visit, including any changes to treatment.

We will give you a diary to make a note of any asthma attacks your child has between visits. We will check your child's inhaler technique and review their asthma action plan (or give them one if they do not have one already). We will also give you a device which records when their asthma inhaler is taken. This allows us to see whether any asthma symptoms might be due to forgetting to take the inhaler. Here are some photos of inhalers with their logging devices. The logging device will only go on your child's "preventer" inhaler. They will not have a logging device on their "reliever" inhaler.

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The second, third and fourth visits will last for 30-60 minutes and will take place about three, six and nine months after the first visit. We will ask you to fill in a questionnaire about your child's recent asthma symptoms, and ask you whether they have had an attack since the last visit, and if so what happened. We will measure lung function and height (just like at a normal asthma clinic). We will download the information on your child's inhaler device. We will also measure exhaled nitric oxide. We will only tell you the results of the nitric oxide measurements if you are in the group where symptoms and nitric oxide are being used to guide asthma treatment.

At the end of the visit, your child's asthma treatment may stay the same or may change. We will write to your child's GP with all the details of the visit, including any changes to treatment.

The last visit will last for up to 60 minutes and will take place about twelve months after the first visit. This will be almost the same as the second, third and fourth visits. We will measure lung function and height. We will download the information on your child's inhaler device and measure exhaled nitric oxide. We will also weigh your child and ask you to complete a questionnaire which tells us about your child's asthma and their recent symptoms, and how asthma affects their quality of life. We will ask you whether they have had an attack since the last visit and if so what happened.

At the end of the visit, your child's asthma treatment may stay the same or may change. Just like before, we will write to your child's GP with all the details of the visit, including any changes to treatment. If your child is in the group where nitric oxide is not used to guide treatment we will write to you after the last visit with the nitric oxide results.

The table below summarises what would happen at each visit.

	First visit	Second, third and fourth visits	Last visit
Exhaled nitric oxide	✓	✓	✓
Questionnaire	✓	✓	✓
Lung function and height	✓	✓	✓
Weight	✓		✓
Inhaler log data		✓	✓

In order verify asthma attacks reported the clinic appointments we would use data that is collected routinely in the NHS, for example about clinic appointments, hospital admissions and prescriptions

There are no blood tests at all.

Long term follow-up in RAACENO

We plan to try and obtain funding to follow up the children who take part in the RAACENO study beyond the 12 month follow-up period. We would like to do this to see how health changes over time and impacts on their life. To do this, we would use data that is collected routinely in the NHS, for example about clinic appointments, hospital admissions and prescriptions. **There would be no additional visits or questionnaires involved in this longer-term follow-up**.

We could get routinely collected NHS data from hospital and GP medical records – this would be done by someone who has permission to look at medical records. Alternatively, we could get routinely collected data from NHS and other government central data registers. Across the UK, there is the Office for National Statistics. In addition, in England there is NHS Digital, in Scotland the Information Services Division, and in Wales the NHS Wales Informatics Service. To get data from central data registers like these, we would securely send them some information about your child (e.g. date of birth, name, and address). They would then match this information to their records and securely send us information using your child's study number (and not their date of birth, name or address). As with all information collected within the main RAACENO study, this information would be held confidentially and stored securely.

Your child can take part in the main RAACENO study without agreeing to take part in this longer term follow-up.

What are the possible benefits of taking part?

All children will get regular asthma assessments. Asthma treatment is currently only guided by symptoms, and so children in the group where asthma treatment is guided by symptoms will continue to get current best asthma management. We are testing the possibility that using both the breathing test that measures exhaled nitric oxide **plus** symptoms to guide asthma treatment will reduce a child's risk for an asthma attack, but we do not know if this will work until the end of the study. At the end of the study, we will write and tell you the results of the study.

What are the possible risks of taking part?

There are no risks from taking part.

Will participation in the study be kept confidential?

Yes, all the information will be kept confidential. We will follow ethical and legal practice and all information about you will be handled in confidence. All information which is collected about you during the research will be kept strictly confidential and will be held securely in accordance with the Data Protection Act. Data for all participants in the study, including those who withdraw, will be kept securely for a minimum of 10 years. Only certain members of the research team will have access to your information.

The statistical analysis of the study is being conducted at the University of Aberdeen, and to maintain confidentiality, the

statistical team will only analyse anonymous data. (Anonymous data does not include names or addresses, and it is not possible to identify individual participants from anonymous data). Any reports or publications arising from the study will contain anonymous data so that you and your child cannot be recognised from it.

Other researchers may wish to access anonymous data from this study in the future. If this is the case, the Chief Investigator will ensure that the other researchers comply with legal, data protection and ethical guidelines.

If your child joins the study, the data collected for the study, together with any relevant medical records, may be looked at by authorised persons from the University of Aberdeen and the Research and Development Department of your local NHS Organisation to check that the study is being carried out correctly. All will have a duty of confidentiality to you and your child as a research participant.

Expenses and payments

You can receive travel expenses to attend your local study centre. Please ask your research nurse for information about how to claim travel expenses.

What will happen to the results of the research study?

We will share the results of the study with doctors across the UK who look after children with asthma. The results will be published in scientific journals and presented at scientific meetings. We will also send you a summary of the results.

Who is organising and funding the research?

This study is being organised by asthma doctors at the University of Aberdeen and elsewhere in the UK. The research is being funded by the Efficacy and Mechanism Evaluation (EME) Programme, a Medical Research Council and NHS National Institute for Health Research partnership.

The study is being co-ordinated by the Centre for Healthcare Randomised Trials (CHaRT), a registered clinical trials unit at the University of Aberdeen.

Who has reviewed this study?

The study has been reviewed by the North of Scotland Research Ethics Committee and also specialists in the field.

What if I want to complain?

If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek compensation through the research sponsors of the study - the University of Aberdeen and NHS Grampian. Contact details for both research sponsors are available through the research team.

As a patient of the NHS if you are harmed due to someone's negligence, then you may have grounds for a legal action, but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms would be available to you.

If you have a concern about any aspect of this study you should ask to speak to the study doctors who will answer your questions (contact details are at the end of this information leaflet). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints mechanisms (or Private Institution). Contact details can be obtained from your local hospital.

What do I do now?

If you and your child are interested in taking part in this study or if you require any further information, please contact us. Our contact details are below.

{Insert local contact details}

Thank you very much for taking the time to read and consider your participation in this study.