

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

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We would like to invite you to take part in a research study which will see if taking a breathing test every three months can help prevent asthma attacks. Take your time to decide. You should know why the study is being done and what it will mean for you. Please take time to read this information leaflet and to talk with family and friends if you want. Ask us if there is anything that is not clear or if you would like to know more.

Thank you for reading this.

What is the purpose of the research study and why is it being done?

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 you about how your asthma has been and any coughing or wheezing, and how often you use your blue inhaler. The doctor or nurse uses this information to help decide whether your asthma inhalers and any other medicines that you take 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 your doctor or nurse to make these decisions about 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 have I been chosen?

Your hospital doctor has told us that you have asthma and have had an asthma attack in the last year.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you choose to take part, you can stop at any time and you don't need to say why.

What happens if I take part?

If you take part in the study we would like you to come to your local hospital every three months for a year. These visits will replace the asthma clinic appointments you have with your hospital asthma doctor. Your asthma hospital doctor will still be available to speak to you if you want.

The first visit will last up to 90 minutes. During this time we will ask you about your asthma, and also ask you to fill in a questionnaire about your asthma symptoms. We will measure your height, weight and lung function (just like a regular asthma clinic). We will also measure your exhaled nitric oxide by asking you to breathe out slowly into a small machine for six to ten seconds (see photos on the next page). You can also see a video of these tests on 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 you will be put in one of two groups by a computer which sort of flips a coin. Either

- you will be in the group where asthma treatment depends on asthma symptoms only
- OR
- you be put in the group where asthma treatment depends on asthma symptoms plus exhaled nitric oxide levels.

Whichever group you are in, your asthma treatment may stay the same or be changed slightly. There will be no big changes to your asthma treatment.

Just like a normal asthma clinic, at the end of the visit you will get a prescription to go to the hospital pharmacy for any changes to your medication. We will also write to your GP and your hospital asthma doctor and tell them whether your treatment has been changed or not. We will give you a diary to make a note of any asthma attacks you have between visits. We will check your inhaler technique and look at your asthma

action plan (or give you one if you don't have one already). We will also give you a device which records when you take your asthma inhaler. 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 these with their logging devices. The devices would only go on your "preventer" inhaler, which you probably leave at home during the day. You don't need to have a device on your "reliever" inhaler that you take to school or when you go out.



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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 about your cough, wheeze and need for your blue inhaler and whether you have had an asthma attack since the last visit (just like a normal asthma clinic). We will measure your lung function and height again (just like a normal asthma clinic). We will download the information on your inhaler device. We will measure exhaled nitric oxide. You will only know the exhaled nitric oxide results if you are in the group where symptoms and nitric oxide levels are being used to guide asthma treatment. Your asthma treatment may stay the same or may change slightly. We will write to your GP and your asthma hospital doctor with all the details of the

visit, including any changes to treatment (just like after a normal asthma clinic).

The last visit will last for up to 60 minutes. This will be just like the second, third and fourth visits plus some questions about how asthma affects you. We will also weigh you. Just like before, we will write to your GP and your asthma hospital doctor saying how you are doing and what treatment you are on. Your hospital asthma doctor will see you in clinic three to six months after the last study visit. If you are in the group where nitric oxide is not used to guide treatment we will write to you after the last visit with your nitric oxide results.

The table below summarises what would happen at each appointment.

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

After the last visit, we will also collect information about asthma attacks using data that is collected routinely in the NHS, for example about clinic appointments, hospital admissions and prescriptions.

There are no blood tests at all.

There are also optional parts to the study which will take another 30 minutes at the first visit and 20 minutes at the

second visit. You can take part in the main RAACENO study without taking part in any of these optional parts of the study. You also have the choice to take part in some or all of the optional parts. Young people in both the study groups can do the optional parts.

The information we get from these optional parts of the study will help us understand how the study is affecting the allergic cells in the lungs and also whether nitric oxide may be better at guiding asthma treatment in certain individuals, for example those with allergy.

The optional parts are:

An additional lung function test. At the first visit only, we would ask you to do another lung function test after you have used your inhaler.

Skin allergy testing. Some people with asthma are allergic to things like dust, cat and egg. We call these things allergens. At the first visit we would do skin allergy testing. This involves putting drops of water containing things that you might be allergic to (e.g. dust, cat, egg and pollen) on the inside of your forearm and then scratching the skin under the drop. You will get some itching (a bit like a midge-bite) which will last for between 15 and 30 minutes. If you don't do this at the first visit, but then change your mind, you can ask to do this at one of the other study visits.

Collect some mouth spit. At the first visit we would ask you to rinse your mouth with some tap water and spit this into a container. We would then test the sample for genes that are

related to asthma and allergy. If you don't do this at the first visit, but then change your mind, you can ask to do this at one of the other study visits.

Collect some coughed-up spit. At the first and second visit we will also ask you to cough up some spit from your lungs. To help you cough we will ask you to breathe in a salty mist for 5 minutes. This will help you cough. This might make you wheeze so we will ask you to take your blue inhaler and test your lung function before you inhale the salty mist. Sometimes people need a second 5 minutes of breathing in the salty mist before spit can be coughed up. We will look at the cells in the coughed up spit to see how many airway inflammation cells are present (the cells called eosinophils). We will also test this sample for any bugs.

Remember, you can take part in the main study without taking part in these optional parts of the study.

You can a video of these tests at www.raaceno.co.uk.

If you are in the group who know their exhaled nitric oxide results we would like to know what you think of the study. There is a separate information sheet to explain this part of this study which we will give you at the fourth visit. Please let us know if you would like to know more about this other completely optional part of the study.

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.**

What are the possible benefits of taking part?

You will get regular asthma assessments. We do not know if adding the breathing test that measures exhaled nitric oxide levels will reduce asthma attacks 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?

The optional allergy testing may cause your to have an itchy arm for a short time. The optional coughing up spit test may make you cough and possibly also wheeze but we will only do this test after you have had your blue inhaler and checked your lung function. The salty mist that we will ask you to breathe in as part of this test will taste salty and you can have a drink afterwards to take away the taste.

Will participation in the study be kept private?

Yes, all the information will be kept private. Only certain members of the research team will have access to your information.

How long will the study last?

The whole study will last for 3 years. Each person who takes part in the study will be in the study for 1 year. During the year, there will be five study visits, each lasting about 30

minutes (slightly longer for people who also take part in the optional parts of the study).

Who is leading the study?

The study is being led by a hospital asthma doctor in Aberdeen called Dr Steve Turner. He is helped by asthma doctors from across the country.

Your doctor is also taking part in the study. You can see pictures of some of the other doctors and nurses who are taking part in the study on our website: www.raaceno.co.uk.



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 do I do now?

If you are interested in taking part please let your parent/guardian know.

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