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 study which will see if taking a breathing test every three months can help prevent asthma attacks. Please talk with family and friends about the study.

Thank you for reading this.

Why is this study being done?

Usually at an asthma check up the doctor or nurse will measure your lung function and ask how your asthma has been. The doctor or nurse uses this information to help decide whether your asthma inhalers and any other medicines you take should stay the same, or be changed. The inhalers and any other asthma medicines that you take are designed to help your breathing and reduce the number of asthma attacks that you have.





This picture shows a boy having his lung function measured. You might have seen a similar machine, or one that looks a bit different.

We are doing this study to see whether adding a breathing test to usual asthma check ups at the hospital makes children have less asthma attacks. The test uses a machine to measure a gas that we all have in our breath called nitric oxide.

Here is a photo of the machine that measures nitric oxide levels



having a breathing test. She is blowing into the machine that measures nitric oxide levels in her breath

Here is a photo of a young girl



NIOX VERO®

Boys and girls with asthma have more nitric oxide than children without asthma. Levels of nitric oxide in our breath go up and down. Measuring the nitric oxide levels might help doctors decide whether or not a child's asthma inhalers should be changed to help their breathing and try and stop them having an asthma attack.

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. If you choose to take part, you can stop at any time and you don't need to say why.

What would I have to do if I take part in the study?

You would come to the hospital every three months for a year and instead of seeing your hospital asthma doctor you will see a special nurse. Your hospital asthma doctor will still be available to speak to you if you want.

The first visit will last up to 90 minutes. We'll ask some questions about your asthma. We will see how tall and heavy you are and do your breathing test (just like a regular asthma clinic). We will also measure the nitric oxide in your breath. To do this you breathe out slowly into a small machine for six seconds (see photos on the previous page). You can also see videos of this on www.raaceno.co.uk.

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 (this is what normally happens in the asthma clinic)

OR

 you will be put in the group where asthma treatment depends on asthma symptoms <u>plus</u> the levels of nitric oxide in your breath.

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

We will check how you take your inhaler and chat with you and your parent/guardian about how to look after your asthma. We will also give you a little meter which records

when you take your inhaler. Here are some photos of inhalers with a meter. The meter would only go on your "preventer" inhaler, which you probably leave at home during the day. You don't need to have a meter 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.

We will ask you and your parent/guardian about your asthma. We will do your lung function and see how tall you are. We will look at the inhaler meter. We will measure your breathed out nitric oxide. Your asthma treatment may stay the same or may change slightly.

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. Your hospital asthma doctor will see you in clinic three to six months after the last study visit.

There are no blood tests at all.

There are other parts to the study which you don't have to do. These other parts would take another 30 minutes at the

first visit and 20 minutes at the second visit. If you want to take part in the main study but not in these parts, please tell us. If you want you can "pick and mix" and do some of the other parts below, but not all of them. The other parts are:

- Another lung function test after you have used your blue inhaler.
- Some children with asthma are allergic to things like dust, cat and egg. We call these things allergens. One part of the study is to have a test for allergic reaction. In this test we will put drops of water which have a bit of these allergens in them on your arm. We will then very gently scratch the skin under the drop. You will get a bit itchy for about 20 minutes.
- To collect some spit from your mouth. We would collect this in a small container. We will test the spit for genes that are related to asthma and allergies.
- To collect some coughed-up spit from your lungs. To cough up spit from your lungs we would ask you to breathe in a salty mist for 5 minutes. We will ask you to take your blue inhaler before this to stop you wheezing. We would collect any coughed up spit in a small container. We will test this spit for cells related to asthma and for any bugs.
- To find out how you are getting on in the future by collecting information from the records that are kept about you by your doctor and the hospital.

This website shows you how it is all done www.raaceno.co.uk

You can take part in the main RAACENO study without taking part in these other bits of the study.

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.

What do I get from taking part?

You will get regular asthma assessments. We do not know if adding the breathing test that measures breathed out 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 might go wrong?

The allergy test will give you an itch. The coughing up spit test may make your cough. The salty mist will taste salty and you can have a drink afterwards to take away the taste.

Will everything be kept private?

Yes.

Who is leading the study?

The study is being led by a hospital asthma doctor in Aberdeen called Dr Steve Turner – this is a photo of him. He is helped by hospital 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



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 this information and to consider taking part in this study.