



## SPIROMetry to Manage Asthma in Children

We would like to invite you to take part in a research study which will see if taking a spirometry breathing test every three months can help prevent asthma attacks. Please take your time to decide whether you want to take part or not.

This information sheet will explain 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?

Usually at an asthma check-up the doctor or nurse asks you about how your asthma has been; for example if you have been coughing or wheezing, and how often you need your blue inhaler. The doctor or nurse uses this information to help decide whether your asthma preventer inhalers and any other medicines that you take should stay the same or be changed.

Often at an asthma check up the doctor or nurse will also ask you to do a breathing test where you blow into a machine to see how well your lungs are working. You might have heard the doctors and nurses calling this spirometry or a lung function test.

*Here is a photo of a teenager doing spirometry*



Asthma specialists don't know how best to use the results from spirometry to help decide whether your asthma preventer treatment (including inhalers and tablets) should stay the same or be changed.

We are doing this study to see whether using spirometry can help doctors and nurses make decisions about the asthma preventer treatment in children and reduce the chance of having an asthma attack.

In this study children who take part will be placed into one of two groups. One group will have their asthma managed in the normal way, i.e. we will ask about their cough, wheeze and

how often they need their blue reliever inhaler. A second group will have their asthma preventer treatment guided by both spirometry and cough, wheeze and how often they need their blue reliever inhaler. A computer “decision tool” (also called an algorithm) will look at a number of things including how much asthma treatment you are needing and if you have had a recent asthma attack. The algorithm will then recommend whether your treatment will stay the same or change. Doctors and nurses will then decide whether to follow this advice. 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 we need 550 children with asthma from up and down the UK.

### **Why have I been chosen?**

Your 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?**

You would come for an appointment every three months for a year. These appointments will usually replace your normal asthma check-ups at your local hospital or GP surgery.

**The first visit** will last up to an hour. During this time we will ask you about your asthma, and also ask you to fill in questionnaires about your asthma symptoms (your cough, wheeze and how often you use your blue inhaler) and how your asthma affects you. We will measure your height and weight. We will ask all those who take part to do spirometry.

We would also like to measure the amount of a gas called nitric oxide (or FeNO) that you breath out. Everyone breathes out nitric oxide, but people with asthma have more nitric oxide in their breath than people without asthma. We will measure your nitric oxide levels 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 the SPIROMAC website [www.spiromac.co.uk](http://www.spiromac.co.uk).

Here is a photo of a teenager blowing into the nitric oxide machine...



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



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At the end of your first visit we will put you in one of two groups. We do this using a computer which sort of flips a coin.

- Half of the children who take part in the SPIROMAC study will be in the group who have their asthma treatment based on their symptoms (this is what normally happens in the asthma clinic).
- Half of the children will be in the group where asthma treatment depends on asthma symptoms plus the information from the spirometry test.

When the study is finished, we compare how many children have had asthma attacks in each group.

While you are taking part in the study, you won't know which group you are in, but we will tell you when the study is finished.

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.

At the end of the visit we will write to your GP and your hospital asthma doctor letting them know what your preventer treatment is. If your treatment changes, we will either give you a prescription to go to the hospital pharmacy to collect this or we will ask your GP to write out a new prescription for you to get the new treatment from your local pharmacy.

We will give you a diary to make a note of any asthma attacks you have.

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 (called a logging device or a smart inhaler) 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 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 between half an hour and an hour and will take place about three, six and nine months after the first visit. We will ask you about your asthma symptoms (your cough, wheeze and how often you need your blue inhaler) and whether you have had an asthma attack since the last visit (just like a normal asthma clinic).

We will ask you to do spirometry and measure height again. We will download the information on your inhaler logging device. We will also measure your nitric oxide.

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 an hour. This will be just like the second, third and fourth visits plus some questions about how asthma affects 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.

**There are no blood tests at all.**

The table below sums up what happens at each appointment.

	First visit	Second, third and fourth visits	Last visit
Spirometry	✓	✓	✓
Nitric oxide	✓	✓	✓
Questionnaire about your asthma symptoms	✓	✓	✓
Questionnaire about how your asthma affects you	✓		✓
Height	✓	✓	✓
Weight	✓		
Inhaler logging device		✓	✓

## **Collection of spit samples**

There is another part to the SPIROMAC study that you can take part in if you want. But you don't have to do it if you don't want to. In this part of the study we would collect some spit from your mouth. We would ask you to rinse your mouth with water and spit it into a small container. We plan to test the spit for genes that are related to asthma and allergies.

**You can take part in the main SPIROMAC study without giving a spit sample.**

## **What are the possible benefits of taking part in SPIROMAC?**

You will get regular asthma assessments. We do not know if using spirometry 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 disadvantages of taking part?**

Sometimes doing the spirometry can make children cough.

## **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?**

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 between half an hour and an hour.



### **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 and nurses 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.spiromac.co.uk](http://www.spiromac.co.uk)

### **Who has reviewed this study?**

The study has been reviewed by West Midlands - Black Country 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. If you have any questions that you would like to ask the study team can help answer these.

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