

SPIROmetry to Manage Asthma in Children

We would like to invite you to take part in a study which will see if taking a breathing test called spirometry every three months can help stop asthma attacks. Please talk with your family and friends about whether you want to join the study.

Thank you for reading this.

Why is this study being done?

Often at an asthma check up the doctor or nurse will 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.

Children who come to asthma clinics often do spirometry at the clinic. But doctors and nurses don't know how to use the information they get from the test to decide what inhalers and other asthma medicines that children should take.

The inhalers and any other asthma medicines that you take help your breathing and stop you having asthma attacks.





This picture shows a boy doing spirometry. You might have seen a similar machine, or one that looks a bit different.

We are doing this study to see whether using spirometry will reduce the chances of children having an asthma attack.

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. 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 for an appointment every three months over a year. These appointments will be at the hospital or local doctors. Instead of seeing your usual asthma doctor or nurse you may see a special nurse. Your usual asthma doctor or nurse will still be available to speak to you if you want.

The first visit will last up to an hour. We'll ask some questions about your asthma, including about how asthma affects you. We will measure your height and weight and do spirometry.

We will also measure a gas called nitric oxide in your breath. Everyone has nitric oxide in their breath. Children with asthma have more nitric oxide than children without asthma. To measure nitric oxide, we will ask you to breathe out slowly into a small machine for six seconds. You can also see videos of this on the SPIROMAC website www.spiromac.co.uk.

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



NIOX VERO®

Here is a photo of a young girl having a breathing test. She is blowing into the machine that measures nitric oxide levels in her breath



At the end of the first visit we will put you into a group.

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. But there will be no big changes to your asthma treatment.

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.

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 gadget which measures when you take your inhaler. Here are some photos of inhalers with the gadget. The gadget would only go on your "preventer" inhaler, the one you take twice every day and which you probably leave at home during the day.



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The second, third and fourth visits will last between half an hour and an hour. We will ask you and your parent/guardian about how your asthma has been. We will ask you to do the spirometry and measure your height. We will look at the recordings from the gadget on your inhaler. We will measure your nitric oxide. Your asthma treatment may stay the same or may change slightly.

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. 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 says what happens at each appointment.

	First	Second, third	Last
	visit	and fourth	visit
		visits	
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 spit into a small container. We will 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.

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 up to an hour.

What do I get from taking part?

You will get regular asthma check ups. We do not know if using the results from the spirometry will make you have fewer 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.

Will the spirometry test hurt?

No. The test doesn't hurt. But sometimes doing the breathing tests can make children cough.

Will everything be kept private?

Yes.

Who is leading the study?

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



What do I do now?

If you would like to take part in the SPIROMAC study, please let your parent/ guardian know.

Thank you very much for reading the information about this study.