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**Improving asthma treatments for children and young people**

Information sheet for children and young people

**What’s it all about?**

We are a group of medical researchers working on treatments to help children and young people with asthma. We would like to try a different way of finding the best treatment for your asthma and hope that you may like to take part in our clinical research.

**Why me?**

We are asking 200 children and young people with asthma to take part in our research. We are asking you to take part because your doctor has told us that you have asthma and that you use a ‘preventer’ (brown) inhaler, a ‘reliever’ (blue) inhaler, and also take another medicine (called a Stage 3 Defence) to help control your asthma. We want to find better ways of finding the right ‘Stage 3 Defence’ medicine for children and young people. There are currently two different medicines used as ‘Stage 3 Defence’, and we are looking at a new way of working out which will be better for a particular child. At the moment we usually give a drug called ‘Exhalin’ to children because overall it seems to work best – but we know that some children do better on a different drug called ‘Verabreath’. We want to find why some children do better on Verabreath so that they can get the best treatment straight away.

We all inherit genes from our parents, and sometimes our particular genes affect how we react to medicines. Children who happen to have a particular gene (called the ‘MAS’ gene), seem to react to Stage 3 Defence medicines differently from children who don’t. We want to find out if this is why some children do better on Verabreath instead of Exhalin.

In order to find this out, we will split the 200 children who take part into two groups of 100. One group will be tested to see if they have the MAS gene, and if they do have it, then they will be given Verabreath. Everyone else will be given Exhalin. You will not be told which drug you will take before the study begins.

**What do I have to do?**

If you would like to take part in the study you will need to talk to your parents – we will write a letter to your parents to tell them about our research to make sure they are happy for you to take part. You can only take part if your parents are happy for you to do so.

Two weeks before we ask you to take either Exhalin or Verabreath, we will ask you to stop taking your current Stage 3 Defence drug so that it is ‘washed out’ of your body. As part of trying the new treatment, we will randomly put you into a group (either Group 1 or Group 2).

If you are in Group 1, we will do a test to find out whether you have the MAS gene. To test this, we will take some of your saliva (spit) using a cotton swab. We do not need to take any blood samples from you. If you are in Group 1 and have the MAS gene, we will give you Verabreath. If you do not have the MAS gene, we will give you Exhalin.

If you are in Group 2, we will not test your genes. Everyone in Group 2 will be given Exhalin.

We would like you to try the new treatment for one school year (from September 2014 - July 2015). Over the school year, we want to find out how you are feeling – has your asthma improved? Have you missed school because of your asthma? To find out how well you have been we will ask you to complete an online questionnaire. We would like you to fill in this questionnaire at three different stages:

* at the start of the research (i.e. before you stop taking the Stage 3 Defence drug you use at the moment),
* after the first two weeks (i.e. after you have stopped using your current Stage 3 Defence drug) and then
* every 3 months after starting the new treatment for the school year.

We will also ask you to come to the hospital at four different times during the study – this is so that we can do some extra tests such as testing your lungs and doing some exercise tests to see how well the new treatments work. In addition, we would like to contact your schools to see if you how many times you have been unable to attend. This will help us to find out how the medicine you have taken has affected you.

**Is it dangerous to change my asthma treatment?**

You have been invited to take part in this study because your doctor would like to learn more about how to treat asthma. We will be working closely with your doctor to make sure you do not feel unwell because of a change in your treatment, or that your asthma symptoms are difficult to deal with. If your doctor thinks you would do better on a different treatment to the one that we give to you, you will receive that treatment straight away. Both Exhalin and Verabreath have been used with other people with asthma and are safe to use. However, all tablets and medications can have side effects and your doctor will discuss any possible side effects from Exhalin or Verabreath before you take part in the research study.

**Can I still use my inhalers?**

Yes, we would like you to keep using your brown and blue inhalers when you start the different treatment. The only thing that may change from your treatment at the moment is your ‘Stage 3 Defence’ medicine.

**What will happen with the things I tell you in the questionnaire?**

Everything you say in the questionnaire will be confidential and you will not be identified by name. We will use the things you tell us in the questionnaire to find out how well the Exhalin and Verabreath work – we will do this by adding your responses to those of other young people in the study. This will help us to put together some statistics or facts about children and young people with asthma. The information we find out may be published in an academic journal and may be used to help develop new guidelines for treating asthma. However, we will not include any personal information about you in anything we write.

**Any questions?**

Please ask us or speak to your doctor. You can also email us at: [asthmastudy@research.com](mailto:asthmastudy@research.com)

***Thank you for taking the time to read this information sheet***