



(To be presented on local headed paper)

Centre Name:

Centre Number:

MASCOT – Management of Asthma in School-age Children On Therapy

Young Persons (11-15 Years) Information Sheet and Consent Form (v2.0, 24.07.2008)

Part One: Invitation to take part in a research study

You are being invited to take part in some research. Before you decide if you want to join in it's important to understand why the research is being done and what it will mean for you. So please read this leaflet carefully. Talk about it with your family, friends, doctor or nurse if you want to.

Please ask us if there is anything that is not clear or if you would like more information. Thank you for reading this.

Why are we doing this research?

This study looks at two different medicines called Salmeterol and Montelukast. These are called 'add-on' medicines because we want to see whether they make another medicine, Fluticasone, work better than it does on its own. All three of these medicines are both used already to help children with asthma. We don't know for certain though if Salmeterol or Montelukast make Fluticasone work better or if it works just as well on its



own. If the add-on medicines do make Fluticasone work better we want to know if they do this as well as each other or if one is better than the other.

We hope that the results of this research will help us to better treat other young people with asthma.

What is the medicine, device or procedure being tested?

The 'add-on' medicines we are looking at are called Salmeterol and Montelukast. We will also use a medicine called Fluticasone, which all children taking part in the study will be given. These medicines all work to help you to breathe normally and try to prevent you having asthma attacks. They do this in different ways:

- Montelukast is a tablet you take that **reduces the tightness in your lungs**

- Salmeterol is used in an inhaler and **relaxes the muscles in your chest** to widen your airways (the tubes that let air into your lungs)

Fluticasone is also used in an inhaler and makes it easier for you to breathe by **reducing the swelling in your airways**



Some children will be given a placebo tablet, which is a dummy tablet that looks the same as the Montelukast but contains no medicine. This placebo tablet is very safe and has no effect on you. Apart from the placebo, the medicines are all already used by doctors to treat children with asthma but we want to see if any of them work better when used together. There will be three different combinations of medicines being looked at:



- 1.Fluticasone +Salmeterol
- 2.Fluticasone + Montelukast
- 3.Fluticasone + placebo

You and your parents will not be able to choose which combination you take and the medicines will be made to look the same so that you will not know which medicines you are taking. Your doctor and nurse will not know which medicine you are given either but they can find out if they need to.

Why am I being asked to take part?

You were chosen to take part because you have asthma and the medicines you are taking at the moment aren't able to control all of your symptoms.

This project will involve about 900 children like you in Britain.

Do I have to agree to take part in the study?

No – not at all. It's completely up to you! We only want people to take part if they want to so just tell us if you don't. Whatever you decide nobody will mind and it will not affect how you are looked after. If you decide to take part and then change your mind, that's OK too. You can stop at any time and you don't have to give a reason.

If you agree to take part, we will ask you to write your name on a form called an 'assent form'. This is to say you understand the study and what will happen. You will be given your own copy of this form to keep as well as this information sheet.

Your study doctor or nurse may ask if you mind them recording themselves talking to you about the study. This is because a study called **RECRUIT** is being done to find out what it is like for parents and children when they are asked to take part in a study. If you agree, the study doctor or nurse will give your contact details to the researchers running the RECRUIT study. The RECRUIT researchers might then contact you to ask some more questions. If you decide you do not want anyone to listen to the recording, that is OK too, and it will be deleted.



What will happen to me during the study if I agree to take part?

If you take part you will be involved in this study for one year. During this time you will visit your study doctor or nurse five times. Each visit will probably last for about an hour. The study nurse will also speak to you and your parents on the telephone once.



At your first visit you will see either the study doctor or nurse and they will talk to you about the research. If you say yes to joining the study, you will need to answer some questions and tell the doctor or nurse about how your

asthma affects you. They will also look you over to check that you are well enough to be in the study.

The nurse will give you and your parents some ideas about how to manage your asthma better and give you some advice on using your inhaler to make sure you're using it properly. You will also be given a new inhaler to use. For the next four weeks, you will use all of the tips and advice the nurse has given you to see if it makes your asthma any better.

After four weeks you and your parents will go back to the doctor or nurse. We will ask you and your parents whether you are happy to carry on doing this research. They will ask you some questions about how your asthma has been since your last visit and will measure how well you can breathe. If everything is OK and you still want to take part in the study your parents will be given your medicine.

You will need to take one suck from your inhaler twice a day and a tablet once a day for the next 48 weeks.

You will need to visit the nurse three more times over these 48 weeks. They will ask how your asthma has been and make sure you have enough medicine.

At the end of 48 weeks you and your parents will visit the doctor or nurse for the last time. You will need to answer some questions and have your breathing measured. They will check that you are well in the same way that they did at the beginning of the study.

What will I be asked to do?

During the study you will be asked to take some medicines to see if they help to control your asthma symptoms. You will have an inhaler that you will need to use twice a day and you will also need to take one tablet every day.

You will need to visit your study doctor or nurse five times over the year you will be taking part in the research and let them check you are well at the start and the end of the study. You will be asked to write down any symptoms you have in a special diary, which the nurse will ask to look at.



What other treatment could I have instead?

There are a few different medicines used for young people with asthma. If you were not taking part in the study, you would have been given the medicine your doctor thought would work best for you. The study medications are used to treat children with asthma anyway so you might have received one of them even if you weren't taking part in the study.

Will the medicine upset me?

Sometimes medicines upset our body and if this happens we call them side-effects. Fluticasone, Salmeterol and Montelukast have been given to lots of children with asthma before so we know they are safe. Some children who are given these medicines may get some side effects though. The most common ones are:

- itchy or sore throat
- chest infections
- croaky voice
- headaches
- muscle cramps
- shaky feeling (called 'palpitations')



Is there anything else to be worried about if I take part?

People sometimes worry about whether the things they say will be kept private. In this study the only time we would ever tell somebody what you have said is if something made us concerned about you and your safety. Apart from that, everything you tell us is private.

Will the information about me be kept private?



When we write down information you or your parents tell us we will give you a number. We will use this number instead of your name so no-one will know the information is about you. Of course you can tell your family and friends about it if you want to. When we have finished the study we will write reports about it, but these reports won't have your name on them.

What are the possible benefits of taking part?

We hope that your asthma will get better from taking part in this research but we cannot promise that it will. You will not know this until you start taking the new treatments. The information we get might help treat other young people in the future though who have asthma.

Who can I contact for further information?

If you have any questions at all, at any time, please contact:



Your Research Nurse:

study nurse name & telephone/email

The other people helping with this study are:

Research Doctor: Dr? (telephone number)

Thank you for reading so far. If you are still interested, please read Part Two.

Part Two: Information you need to know if you still want to take part.

What happens when the research study stops?

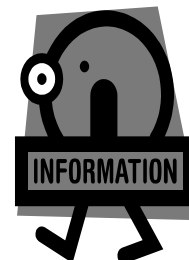
When you have finished taking part in the study, your family doctor (GP) will be told what medicine you have been taking. If that medicine has improved your asthma then you will be able to talk to your doctor about taking it again. Your doctor will tell you what they think is best.

What happens if new information about the research medicine comes along?

Sometimes during research, new things are found out about the research medicine. Your doctor will tell you all about it if this happens. What is best for you might be:

- To carry on taking part in the study
- To stop taking part and have the usual treatment that your doctor prescribes

If new information about the research medicines comes along, we will tell you and your family about it and you can all decide if you want to carry on taking part in the study. You will be able to ask us any new questions you have. It is OK if you decide that you don't want to take part anymore because of something new you find out. If the new information says that the medicines do not work as well as we think they do, then we will stop the research.



What if there is a problem or if something goes wrong?



If you have a question about any part of the study, you should ask the researchers and they will do their best to answer anything you are worried about. If you are still unhappy and wish to complain to someone else, you can do this using the NHS Complaints Procedure. You might need to ask your family to help you with this.

Will anyone else know I'm doing this?

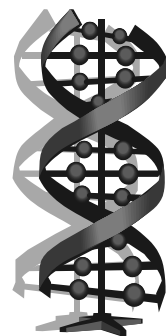
Yes –

- The researchers who are running the study or research inspectors might want to see your medical notes to make sure the research is being done properly.
- Your family doctor will be told you are taking part

If you agree to take part in the research, any of your medical records may be looked at to check that the study is being done properly. So that we can check you agreed to join in the study a copy of the forms you and your parents signed to give us permission for you to be in the study will be sent to the Clinical Trials Unit (CTU) who are running the research. The CTU will not tell anyone else your name and the form will be kept in a locked cupboard.

What are genetic tests and will any be done?

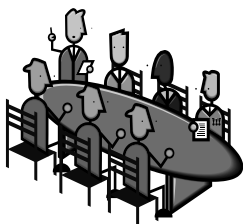
We would like to collect a genetic sample from all of the children in the study. This is an extra study and you do not have to give us the sample. Your doctor or nurse will collect the sample just by asking you to spit into a special tube. That is all you have to do. **You can still take part in the main study, even if you say no to this part.** Another information sheet explains this part of the study. If you say yes you will need to write your name on another 'assent form' to tell us you understand what will happen to you and are happy to do this.



Who is organising and funding the research?

The NHS Health Technology Assessment Programme has provided the money to carry out this study. University Hospital of North Staffordshire NHS Trust, Keele University and the University of Liverpool are organising the study.

Who has reviewed the study?



Before any study is allowed to happen, it has to be checked by a group of people called a Research Ethics Committee. The Research Ethics Committee is a group of experts and ordinary people who look at studies very carefully to decide whether they are OK to do. The North West Research Ethics

Committee have looked at this study and decided it is OK.

Thank you very much for taking the time to read this. Please ask any questions if you need to.



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**Assent Form for Young People (v2.0, 24.07.2008)
(to be completed by the young person and their parent/guardian)**

Young person (or, if unable, parent on their behalf) to circle all they agree with:

- Have you read (or had read to you) the information about this study? Yes/No
- Has a doctor or nurse explained this study to you? Yes/No
- Do you understand what this study is about? Yes/No
- Have you asked all the questions you want to? Yes/No
- Have you had all of your questions answered in a way you understand? Yes/No
- Do you understand that it's OK to stop taking part at any time? Yes/No
- Are you happy to take part in this study? Yes/No
- Are you happy for this conversation to be recorded for RECRUIT?* Yes/No
(*delete if not applicable to this centre)

If ANY answers are 'No' or you don't want to take part, DON'T sign your name!

If you **DO** want to take part, please write your name and today's date below:

Your name _____

Date _____

Your parent/guardian must write their name here too if they are happy for you to take part:

Sign _____

Print _____

Date _____

The doctor or nurse who explained this study to you needs to sign too:

Sign _____

Print _____

Date _____