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

Information sheet for parents/guardians

**What’s it all about?**

Your son/daughter is being invited to take part in a clinical research study on asthma treatments for children and young people. We are asking 200 children and young people between the ages of 7-18 years with asthma to take part in the study. We are asking your son/daughter to take part because their doctor has indicated that your child has asthma and uses a ‘preventer’ (brown) inhaler and a ‘reliever’ (blue) inhaler, as well as a ‘Stage 3 Defence’ medicine to help control their asthma.

At the moment there are two different medicines used as Stage 3 Defence medicines, 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 in fact do better on a different drug, called Verabreath. We want to find why some children do better on Verabreath. One theory is that children with a particular gene (called the MAS gene) may be the ones who do better if they take Verabreath.

**What does my son/daughter have to do?**

If your son/daughter would like to take part in this project, we will ask them to take one of two medicines that are both a Stage 3 Defence. Both are licensed and are regularly used in hospitals at the moment.

Your son/daughter’s participation in this project is completely voluntary. If your son/daughter would like to take part we will ask them to sign an assent form similar to the one attached to this information sheet. Even if your son/daughter initially chooses to take part they may withdraw at from the study at any time. Whilst your son/daughter can decide whether they would like to take part in the project, they will require your permission to be involved in the study.

Two weeks before we start the research, we will ask your son/daughter to stop taking their current Stage 3 Defence medication – this is just so we can make sure this medication is ‘washed out’ of the body before the research begins. They should carry on using their brown and blue inhalers as usual throughout the research project.

As part of our research, we will then randomly assign your child to a group: either Group 1 (who will be testing our theory whether testing for the presence of the MAS gene impacts positively) or Group 2 (the ‘control’ group). If your child is allocated to Group 1, we will do a test to find out whether they have the MAS gene – this involves taking some of your son/daughter’s saliva using a cotton swab. We will not be taking any blood samples.

If your child is allocated to Group 1 and has the MAS gene, we will give your child Verabreath. If your child does not have the MAS gene, we will give your child Exhalin. If your child is allocated to Group 2, we will not perform a gene test to see if they have the MAS gene. Each child in this group will be given Exhalin.

We would like your son/daughter to carry on taking either Exhalin or Verabreath for the duration of a school year (September 2014 – July 2015). Over this period, we want to find out how your child is feeling whilst taking the treatment, including any improvements to symptoms, how they respond to exercise, or whether they have missed school because of their asthma. To find out how your child has responded to the different treatment, we will ask them to complete an online questionnaire at various times of the study. For example, we will ask your child to complete the questionnaire at the start of the research (i.e. before they stop using their current Stage 3 Defence drug), after the first two weeks (i.e. after they have stopped using their current Stage 3 Defence drug), and then every three months after starting the new treatment for the school year. We will also ask you and your child to come to the hospital at four different times during the study in order to carry out some additional tests such as lung function tests and exercise tests.

**Is it dangerous for my child to change their asthma treatment?**

Your son/daughter is being invited to take part in this study because his/her doctor would like to learn more about how to treat asthma. We will be working closely with your doctor to make sure your son/daughter is not adversely affected by any change in their treatment or that their asthma symptoms worsen. If your child becomes unwell, and their doctor thinks they will do better on a different treatment, they will be changed to that treatment immediately. 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 either Exhalin or Verabreath with you and your son/daughter before the research begins.

**What will happen with the things my child tells you in the questionnaire?**

Everything your child says in the questionnaire will be confidential and they will not be identified by name. We will use the results from the questionnaire to help find out whether using this gene test helps us work out whether a particular child is likely to do better on Exhalin or Verabreath. The information from the questionnaires will be analysed by our research team. The information we gather 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 your child in anything we write.

**Any questions?**

Please feel free to ask us or your doctor any questions you may have. You can also email us at: asthmastudy@research.com

Professor Sarah Smith

Chair in Paediatrics

University of Hove

ssmith@hove.ac.uk

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