PATIENT INFORMATION SHEET

THERASORB THERAPEUTIC APHERESIS IN ABPA

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. One of our team will go through the information sheet with you and answer any questions you have. This should take about 20 minutes. Talk to others about the study if you wish. Please ask us if there is anything that is not clear.

What is the purpose of the study?

Allergic bronchopulmonary aspergillosis (ABPA) is a condition that affects people with asthma or cystic fibrosis. There is an allergic reaction to a fungus, called Aspergillus fumigatus, and this causes worsening of asthma symptoms, such as cough, wheeze and shortness of breath. At the centre of this allergic reaction is a molecule called IgE and patients with ABPA have very high levels of IgE in the blood.

This study aims to test whether removing this IgE from the blood can lead to a reduction in the symptoms of ABPA and a reduction in doses of medications such as steroids. This would be done by a process called apheresis. Blood is drawn out of the body, passed through a machine to remove the IgE and then is returned to the body.

Why have I been invited?

You have been invited because you have ABPA and may benefit from the effects of this treatment. For our initial study we plan to study a total of five patients.

Do I have to take part?

No. It is up to you to decide to join the study. We will describe the study and go through this information sheet. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive from King’s College Hospital.

What will happen to me if I take part?

This study involves making a number of visits to the Chest Unit at King’s over a period of six months.

On your first visit you will be introduced to an advocate. This is someone who works in our department but who is not directly connected with the running of the study. Their role is to act as an advisor and to help answer any questions you may have about the study. You will

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meet with your advocate every time you attend for the study, and you can contact them between visits if you have any questions.

On the first and eighth weeks you will have blood tests for cell counts, calcium, protein and immunoglobulin levels (molecules that help fight infection) and a blood test to look for worm infection, along with breathing tests (blowing hard into tubes) and a test of how far you can walk in six minutes. You will be asked to complete questionnaires about how well you feel and how bad your symptoms are. On these two visits you will need a bronchoscopy and biopsy, where we will look into your breathing tubes with a small camera and take a sample of the wall of the breathing tube. This will be explained in more detail below.

On days when you come in for Therasorb treatment you will have the same blood tests and then be attached to the Therasorb machine. This will be explained in more detail below. You will have the Therasorb treatment for around three hours on four consecutive days in the first week, and on three days in the fourth and eighth weeks.

After the Therasorb treatment has finished you will come in once a month to have your blood tests and breathing tests repeated and will be asked to fill in the questionnaires. This will be for a period of four months. These visits will typically last around half an hour.

**Bronchoscopy**

In the first and eighth weeks you will have a bronchoscopy. For this, we will ask you to have nothing to eat on the morning of the procedure, but you can have a drink first thing. We would ask you to have someone bring you in who can also accompany you home. Some local anaesthetic spray will be put into your nose and throat, which tastes sour and stings a little, but not for long. After around thirty seconds your throat and nose will be numb. You will be given a small dose of sedation, not to put you to sleep, but just to make you a little drowsy. The bronchoscope, which is a long, thin camera, will be slid into your nose and down into your breathing tubes. Once down there we can take tiny bites (biopsies) of the wall of your breathing tubes and these will be examined under the microscope. The procedure takes around twenty minutes and patients generally tolerate it very well.

While it is a safe procedure, there are a few risks you need to be aware of. It may make you cough a bit and, after biopsies, you can cough up some blood. However, this is usually only a very small amount and settles down by the end of the day. It is possible but unlikely to have a sore nose or a nosebleed after the procedure. You may get a sore throat, but the risk of this is less if you try not to talk when you are having it done. In very rare instances, patients can have breathing problems after the procedure (respiratory failure) but this is usually only patients who have severe breathing problems before the procedure starts. Your breathing is better than this. We will monitor you until the sedation wears off. After two hours your throat will no longer be numb and you will be able to eat and drink.
The purpose of the bronchoscopy is to assess the level of inflammation in your breathing tubes. This will provide useful information on how effective the treatment is but if you are not able to have a bronchoscopy, or choose not to have it done, you will still be able to participate in the study.

**Therasorb treatment**

You will be sat in a comfortable chair and are advised to bring a book or something to do. Two cannulas (intravenous drips) will be inserted, one in each arm, after cleaning the skin and injecting a small amount of local anaesthetic to numb the skin. You will be given an infusion that makes your blood thinner. Your blood will return to normal thickness when this infusion stops. You will be connected to the apheresis machine via this cannula. Blood is taken off, passes through the machine to remove the IgE, and is then returned to your body via the same cannula. This process is continually repeated until the right amount of IgE has been removed. This will typically take between three and three and a half hours. After the treatment has ended we will remove the cannula and repeat the blood tests. The main risk from this procedure is of bruising, as your blood will be thinner than usual. This is usually not severe, and any bruising will fade over time.
A patient attached to the Therasorb machine.

*What type of study is this?*

Because this is a new therapy, we want to test out whether it works to lower the level of IgE in your blood, reduce your symptoms and reduce your need for treatment. We are also interested in your experience in using the treatment: how convenient or inconvenient it is, whether it is uncomfortable, whether you would consider having it again. Your feedback will be a very important part of the results of the study.

*Expenses and payments*

You will be reimbursed for travel expenses for taking part in the study, but we cannot offer you any payment for your time.

*What will I have to do?*

You will need to turn up for treatments at times that will be set out in your treatment schedule. We will ask you to carry on taking your treatments as usual.

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What are the alternatives for treatment

This is a new way of treating ABPA. Alternative therapies are those that your doctor will already have discussed with you, such as inhalers and steroid tablets.

What are the possible disadvantages and risks of taking part?

There are small risks associated with taking part in this study. As detailed above, bronchoscopy can cause coughing and, sometimes, coughing up blood, although this is generally not severe. A sore nose or a nosebleed are possible but not common. Talking during the procedure can make a sore throat more likely. There is a risk of breathing problems (respiratory failure) after a bronchoscopy, but this is very uncommon and usually only would only affect patients who already have severe trouble with their breathing.

The main risk from the Therasorb treatment is of bruising, caused by the blood-thinning medication. If this happens, it is unlikely to be severe and any bruises would fade with time.

IgE is part of the body’s mechanism for fighting parasites. There is a theoretical risk that this treatment could cause a pre-existing parasite infection to come back. The risk of this is very small but we will test for parasites by a blood test at each visit.

What are the potential benefits of taking part?

By removing IgE from the blood, we hope that the severity of your ABPA will decrease. This may lead to an improvement in your symptoms and might even mean you can reduce the dose of some of your medications. Even if there is no direct benefit to you from participating, the information we get from this study will improve the treatment of other patients with ABPA.

What happens with the research study stops?

After the Therasorb treatments, and the period of monitoring, have stopped you will return to your previous treatment regime for ABPA. As things currently stand, you would not have an opportunity to continue with this therapy, even if you find it beneficial as it is not currently available to patients not on research studies in the UK. However, if the research is successful your participation may have helped make it more likely to become part of standard care in the future.

What happens if there is a problem?

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed.

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (020 3299 2075). If you remain
unhappy and wish to complain formally, you can do this through the hospital Patient Advice and Liaison Service (PALS) on 020 3299 3601.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against King’s College Hospital but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

**Will my taking part in the study be kept confidential?**

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence.

All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

**What will happen to the results of the research study?**

Results from this study will be published at conferences or in medical journals. Any results will be anonymised so that it will not be possible to recognise you. You may request a copy of any results that we publish.

**Who is organising and funding the research?**

The study is being sponsored by King’s College London using a grant from the German government. None of the investigators is being paid for including you in the study, or for carrying it out.

**Who has reviewed this study?**

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by King’s Research Ethics Committee.

**Further information and contact details**

You are welcome to contact your advocate at any time during the study period for advice and support. Your advocate’s name is __________________________ and they can be contacted on 020 3299 2075.

If you have any questions about the research project, you can contact Mrs Tracey Fleming on 020 3299 3364.