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Study title:

Investigating pro-inflammatory B-lymphocyte responses in nasal polyps to interleukin-5

PARTICIPANT INFORMATION SHEET

Invitation to participate in research study

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of this study?

Medicines that block an inflammatory chemical messenger in the body – interleukin-5 – have been shown to help treat nasal polyp disease and asthma in some patients. By blocking this chemical messenger these medications are thought to suppress an inflammatory cell type in the airways called eosinophils. However not all eosinophil suppressing medications work as well as each other. Interleukin-5 also affects production of antibodies by another cell type, called B lymphocytes, and potentially this might be another important action of these medications.

In this study we are collecting nasal and blood samples to better understand how interleukin-5 affects antibody responses. We hope what we learn from this study can be used to better design future medications for these diseases.

Why have I been chosen?

You have been chosen to potentially take part in this study as you are due to have a nasal operation and the sample planned to be removed from your nose could be used in our research rather than being destroyed. We are asking for the nasal sample removed during your operation to be donated to our research rather than being destroyed. The operation you have will be the same either way.

You may or may not have asthma or nasal polyp disease – we are looking both for people who have these diseases or who are having nasal operations for other reasons. We may in particular be asking you to take part in this study if you are on a medication that blocks interleukin-5 though most of the participants in this study won’t be on those medications.

Do I have to take part?

It is up to you whether to take part. If you decide to take part, you will be given this information sheet to keep and asked to sign a consent form. If you decide to take part, you are still free to withdraw at any time and without giving a reason. Either way this will not affect the medical care you receive.

Are there any reasons I should not take part?

If you have received certain treatments – Rituxumab or chemotherapy – or have cystic fibrosis or a current infection then you may not be able to take part in this research as your disease might be slightly different. Please ask our study team and we can discuss this with you.

What will happen to me if I decide to take part?

If you decide to take part, we will ask you to donate the tissue (the sample) cut out and removed during your nasal surgery for us to analyse the cells present. Only the routine amount of tissue will be removed - no extra tissue will be taken. If you decide to take part, we will also look through your clinical notes to check why you are having the surgery, any medications you are on or have taken previously, any history of allergic or airway diseases, any previous tests for inflammatory diseases, and any history of smoking. We may ask you these questions if we cannot find the answers in the clinical notes. All information will be treated confidentially and anonymised - you will not be personally identifiable in any of the research. Your GP will not be notified.

We may also ask you to provide a blood sample (up to 20mls). This amount is a small amount but you can decline to give the blood sample while still taking part in the study. Blood sampling is a standard procedure, which may cause discomfort and bruising. If you have a history of any blood disorders including anaemia, please tell the supervising doctor before the blood sample is taken.

We may also ask to place a small sponge / piece of filter paper just inside your nose before the operation to collect nasal fluid from which we can measure inflammatory chemicals in the blood such as interleukin-5. This can be slightly uncomfortable but is very safe. You can decline the nasal sponge / filter paper sample and/or decline the blood sample while still taking part in the study.

What are the benefits of taking part?

There will be no immediate benefits to you for taking part. However this research will help us advance research that in the long-term will contribute to improved treatment and control of lung and nasal diseases.

What happens to the samples obtained from this study?

Our research team processes the samples immediately. Cells from the nasal tissue and blood will be analysed to look for differences in antibody production. The samples will not be used to make any clinical diagnoses.

The scientific tests will be carried out in laboratories at Queen Mary University of London (QMUL), however, some tests on the samples and analysis of the results may be conducted by collaborators outside of QMUL.

Occasionally the samples may contain a slight excess of certain material above the planned requirements. In such cases our normal practice is to anonymously store excess material within the laboratories at QMUL. Your informed consent to this study allows surplus material to be used as a gift for future, related, ethically-approved departmental studies. Any future use of the samples will always be approved by an ethics committee.

The scientific samples are identified by means of a unique research number (and not your name or hospital number) and will not be traceable directly to you in any of the research or by any of the researchers. Results obtained from the samples are treated with the strictest confidence.

How will we use information about you?

We will need to use information from you and from your medical records for this research project. This information will include your:

- Name
- NHS number

People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.
- If you withdraw from the study, we will destroy all your identifiable samples, but will use the data from samples already collected up to your withdrawal.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to data-protection@qmul.ac.uk

How will I find out the results of the study?

Results of the study will be published in scientific journals, although no one will be able to tell that you have participated in the research. You are welcome to look at these publications and the researchers will be happy to provide references or copies of publications if you wish.

Who is organising and funding the research?

This research study is funded by a grant from a commercial pharmaceutical company. The study is led by Dr Louisa James, a senior lecturer employed by Queen Mary, University of London. Members of Dr James' laboratory will perform the research.

What if there is a problem?

All research in the NHS is looked at by independent group, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. A Research Ethics Committee has approved this study. If you have any concerns about this study the researchers will do their best to answer your questions.

If you are still unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure by contacting the patient advisory liaison (PALS):
In person: Royal London Hospital drop in service 9.30am-4.30pm, second floor central tower.
By phone: 020 3594 2040
By email: pals@bartshealth.nhs.uk

In the event that something does go wrong and you are harmed during the research, the insurance that Queen Mary University of London has in place provides "No-Fault Compensation" for participants covering both negligent and non-negligent harm.