Information Sheet for Potential Participants

Genetic variation and mechanisms of inflammatory bowel disease

Principal Investigator: Professor Arthur Kaser

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. This leaflet is designed to help you understand more about our study. Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study. One of the team will go through this leaflet with you in detail if you do decide to participate. Please ask a member of the research team if anything is unclear or you have any further questions.

What is the purpose of this study?

Inflammatory bowel disease is a common condition affecting at least 250,000 people in the UK. It affects the digestive system, and patients typically experience symptoms such as abdominal pain, weight loss, diarrhea and failure to grow appropriately. Many patients need treatment with strong drugs such as steroids to help control symptoms, and may need major abdominal surgery. Whilst current treatments control inflammation, they do not cure the condition.

Recently, a number of genetic markers have been discovered that increase a person's risk of developing inflammatory bowel disease. Many of these are thought to be linked to how the immune system responds to bacteria. However, the ways by which these genetic alterations influence the workings of the immune system and increase the risk of developing inflammatory bowel disease is not yet well understood. In this study, we will investigate how the behaviour of immune cells is affected by genetic variation that has been linked to inflammatory bowel disease. We hope that this will improve our understanding of the immune cells and pathways that are affected in inflammatory bowel disease and ultimately lead to new targets for therapies.

Why have I been invited?

You have been invited to participate as you have previously registered with the Cambridge BioResource and indicated potential interest in participating in studies such as this one. A number of people have been invited to participate with a variety of different genetic signatures in the genes we are investigating.

Certain genetic markers increase the risk of developing inflammatory bowel disease. We would like to investigate how different genetic make-ups affect the behavior of the immune system of healthy people. This will allow us to understand more about how the immune system works and what happens in patients with inflammatory bowel disease.

The immune system can be affected by a number of different medical conditions, including inflammatory bowel disease, kidney and liver disease and HIV, Hepatitis B and C. Unfortunately, if you have one of these conditions, are pregnant, or currently taking steroid tablets then you will not be able to take part in this particular study as the results we obtain from your sample could be affected.

Do I have to take part?

No, it is your decision whether or not you take part in the study. You are also free to withdraw from the study at any point, without giving a reason. Should you decide not to participate or withdraw, your decision will not affect any future healthcare you receive.

What will happen to me if I take part?

If you wish to be involved in this study, please return the enclosed form. An appointment will be arranged at a time convenient for you. This will be in Addenbrooke's Hospital. In some cases, it may be possible for the appointment to take place in your place of work or residence.

At the appointment, a member of the research (or Cambridge BioResource) team will discuss the study with you and answer any further questions you may have. If you would like to participate, we would then ask you to provide a blood sample. The amount of blood required for this study is 45 ml; this volume is roughly equivalent to three tablespoons and is less than 10% of the volume donated in a standard UK blood transfusion. After a blood sample has been taken, no further involvement will be required from you as part of this study.

Will I be re-imbursed for expenses?

Yes, we will repay any expenses you incur for travelling to the hospital appointment.

What are the possible disadvantages and risks of taking part?

It is possible that you may experience some mild discomfort during blood sampling and bruising, which will resolve within several days. Occasionally, some people may experience light-headedness or feel faint during blood sample collection. This should resolve within a few minutes.

What are the side effects of any treatment received?

None – no treatment will be given.

What are the possible benefits of taking part?

Participation in the study will not benefit you directly. We hope that the study will increase our understanding of the immune system and why some individuals develop inflammatory bowel disease. If you would like to be kept updated, we can arrange to send you copies of publications resulting from the study.

What 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. The detailed information on this is given in Part 2.

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. The details are included in Part 2.

PART 2 – TAKING PART IN THE STUDY

If I decide to take part in the study, can I change my mind?

Yes. You can change your mind at any point, without giving a reason. If you decide to withdraw from the study after giving a blood sample, any remaining samples can be destroyed should you wish.

What if there is a problem?

If you have a concern about any aspect of this study, please speak to the researchers who will do their best to answer your questions through the contact details given below. If you remain unhappy and wish to complain formally, you can do this through the NHS complaints procedure or University of Cambridge research complaints procedure.

Will my information be kept confidential?

Yes. All information will be kept strictly confidential in accordance with the NHS code of confidentiality. In the laboratory, the samples you provide will be assigned a three digit identification number which will be linked to the Cambridge BioResource identifier. No identifiable information will be stored in the laboratory. At the end of the study, the linking code will be deleted, meaning that any data stored will no longer be traceable in any way to you.

Will my GP know about my participation?

No. As we will not be collecting or analyzing any data that will be of personal clinical relevance for you, we will not routinely inform your GP.

What will happen to any samples I give?

The sample of your blood will be marked with a unique ten-digit study identification number and processed within our research laboratories. We will extract and grow certain immune cells from your blood sample and investigate how they respond to bacteria. Once the investigations are completed, cells will be destroyed (within five days of the sample collection). We will store extracts of cells in a secure freezer within the Department of Medicine for analysis. Once the study is completed, all material will be destroyed.

Will any genetic tests be done?

Yes. We are interested in how a person's genetic makeup affects the way certain immune cells work. You have been approached to participate in this study based on the results of the saliva or blood sample you donated when you first joined the Cambridge BioResource. In our research, we may need to confirm your genetic signature or define genetic differences more precisely through further specialised genetic tests. However, this information is not clinically relevant and does not allow us to make any assessment of your genetic risk of developing any disease, and we will not be passing any of this information back to you. We will not be determining the entire genetic code of any participant. All genetic information will be stored in the scientific database, separately from your personal information and linked only by your unique ten digit identifier.

What will happen to the results of the study?

We will share the results of the study with the larger scientific and healthcare communities. This may include presentations at conferences, or publication in scientific journals. We may also present results of our research to the wider public at hospital or university open days. Any results published in this way will not include any information that could allow individual research participants to be identified in any way. All publications resulting from the study will be listed on the CBR website.

Who is organising and funding this research?

This research is being undertaken within the Department of Medicine in the University of Cambridge. Funding for this study is from the European Research Council.

Who has reviewed the study?

This study has been reviewed and given a favourable opinion by South Central Berkshire B Research Ethics Committee. This is an independent group of people with experience in reviewing research studies, whose role is to safeguard the rights, safety, dignity and wellbeing of research participants.

The conduct of the research has been reviewed and is subject to ongoing oversight by the Research and Development committee of Addenbrooke's Hospital. Scientific aspects of the study have been reviewed and given favourable opinion by the European Research Council, and by the Cambridge BioResource scientific advisory board.

Who should I contact for further information?

If you wish to require further information about this study, please contact the BioResource study office on (01223) 769215. If after reading this leaflet you feel you wish to learn more about participation in the study, please complete and return the enclosed participation form using the prepaid envelope.

In order to find out more about the research being undertaken in Professor Kaser's laboratory please visit:

http://www.immunology.cam.ac.uk/directory/kaser

Some useful websites with general information about research:
UKCRC Understanding clinical trials
http://www.ukcrc.org/publications/informationbooklets.aspx
INVOLVE - Promotes public involvement in the NHS
http://www.invo.org.uk/

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

If you wish to receive a large print copy of this leaflet, please call (01223) 769215