

Patient information sheet

15 Jan 2015

Thank you for reading this and for considering participation in this study.

Title: “Immune function in Inflammatory Arthritis” COREC06/Q1606/139

Invitation paragraph. 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 and discuss it with friends, relatives and your GP if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this sheet.

What is the purpose of the study? It is thought that abnormalities of the immune system and interactions with gut bacteria are partly responsible for causing some forms of arthritis, which include Rheumatoid Arthritis, reactive arthritis and Ankylosing Spondylitis (AS). We wish to study a small sample of your blood, joint fluid or material (only if being removed as part of your treatment) and perhaps stools, to see if there are any unusual features of the immune proteins, white blood cells or gut bacteria that might trigger disease or cause it to flare. We have been recruiting patients to this study since 2007 and propose to study a further 300 people over the next 3 years.

Why have I been chosen? We wish to study samples from patients with different forms of arthritis and to compare with samples from people without any arthritis. We also wish to compare samples in the same patient before and after treatment.

Do I have to take part? It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be 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. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part? We wish to take 20-25ml (4 teaspoons) of your blood for study purposes. In some patients we may ask to study samples before and during a new treatment and perhaps during a disease flare. The maximum number of time we may ask for a sample is three. If, as part of your treatment, you need joint fluid draining or removal of some of the joint lining (synovial membrane) during any planned surgery, we would also wish to study some of the excess material not required for tests. Up to 30 people may also be approached and asked to consider giving a urine or stool sample, participants would provide the stool sample in their own home, appropriate arrangements will be made for packaging and return the sample. This study will not

involve any tests, procedures or hospital visits additional to your normal treatment, and there are no side effects or risks involved taking part.

What are the possible disadvantages and risks of taking part? The amount of blood being taken is too small to affect your health, having a blood test can result in bruising.

Who has reviewed this study? This study has been approved by the NHS Health Research authority NRES Committee South Central – Oxford C.

What are the possible benefits of taking part? None to you directly. You will help research.

If I make a special journey to give blood will my travel costs be reimbursed? Yes.

What if something goes wrong? If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this study be kept confidential? All information collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital/surgery will have your name and address removed so that you cannot be recognised from it. Your GP will be informed that you have participated but not given any other information.

What will happen to the results of the research study? Arthritis Research UK, The Wellcome Trust and the NIHR Biomedical Research Centre are funding this research. The OUH NHS trust, which is sponsoring it, will be given the results of the study, which will also be published in a medical journal and accessible over the internet through standard search engines or at <http://www.ndorms.ox.ac.uk/research.php?group=ankspnd> Your name will not of course appear in any such publication.

Contact for Further Information:

**Professor Paul Bowness,
Consultant Rheumatologist
Rheumatology, Nuffield Orthopaedic Centre
Windmill Rd, Headington
Oxford 01865-741-155**

Research Nurse Karen Doig, karen.doig@ndorms.ox.ac.uk, 01865 737417

Patient will be given a copy of this information sheet and a signed consent form to keep.