PATIENT INFORMATION SHEET

Rheumatoid Arthritis Medication Study (RAMS):
Predicting Response to DMARDs in Rheumatoid Arthritis

You are being invited to participate 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 and ask for anything that is unclear to be explained.

What is the purpose of the study?

Methotrexate is one of the most common medications used for rheumatoid arthritis. Many patients do very well on this medication and their arthritic symptoms improve considerably. However, some patients do not improve despite therapy. Others may need to stop the medication because they have developed a side effect. The purpose of this study is to see whether we can predict who will do well and who will have to stop using methotrexate.

Why have I been chosen?

You have been chosen to participate in this study as you are about to start a new treatment for your arthritis, called methotrexate.

Do I have to take part?

You do not have to take part. If you do decide to take part, you can keep this information sheet and you will be asked to sign a consent form. If you do 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 to not take part will not affect the standard of care you receive.

What will happen to me if I take part?

Your participation will involve the following:

(i) Agreement to complete the questionnaires and other survey forms about your health. These questionnaires include questions about your health, your physical ability, and your medications. These questionnaires will be given to you when you visit the outpatient clinic at study entry, 3 months, 6 months and 12 months. You may find some of the questions to be of a sensitive nature or personal nature. Filling out the questionnaire should last about 45 minutes. If you need any help with filling out the questionnaire, you may ask a member of your family or a friend, the research nurse or the study co-ordinator (Tel. 0161 275 5663) to help you filling out the questionnaire. We would like to take this opportunity to reassure you that all data received will be treated with the utmost confidence.

(ii) Agreement to complete a diary at home on a weekly basis. This short diary comprises questions about your intake of methotrexate, whether you used any other medication in addition to methotrexate during the previous week, and whether you experienced any side effects because of methotrexate.

(iii) Agreement for your specialist to provide information from your medical records to the researchers from Arthritis Research UK Epidemiology Unit (the University of Manchester), from regulatory authorities or from the NHS trust including: information about medication use, your arthritis, any admissions to the hospital, blood test results such as blood counts, and reports of X-rays.
(iv) Agreement to provide blood and urine samples at the start of your treatment, again in 4 weeks time and then again at 3, 6 and 12 months from the date that you started methotrexate.

(v) Agreement to use these blood samples for the current study.

(vi) Agreement to use these blood and urine samples by other researchers.

(vii) Agreement to use these blood and urine samples for future research.

(viii) Agreement to provide a blood sample which will be used for genetic tests (optional).

(ix) Agreement to be contacted about relevant missing data.

(x) Agreement to provide a blood sample which will be used for genetic tests (optional).

What do I have to do?

Other than your normal treatment and scheduled visits to your rheumatologist, we would ask you to complete our questionnaires on a 6 monthly basis given to you when visiting the outpatient clinic and to fill out the diary on a weekly basis at home. In addition, to let us have samples of your blood and urine at the start of the study, at 4 weeks, and at 3, 6 and 12 months. These samples will either be collected during your blood monitoring visit for methotrexate to the outpatient clinic in the hospital or at your general practitioner surgery.

What will happen to the blood and urine samples taken as part of this study?

When you attend for your routine methotrexate blood tests, we will collect a few additional samples of blood and keep some of your urine. The blood and urine samples collected as part of this research study will be stored centrally at a laboratory at the Arthritis Research UK Epidemiology Unit, The University of Manchester. These samples are stored under strict security and are given a code so that researchers receiving your samples do not know your name or other personal details. Your blood and urine samples will be tested for clues (proteins and related substances) to help explain how you respond to methotrexate. Some blood samples will be used to measure DNA and RNA for (epi)genetic studies of rheumatoid arthritis and response to methotrexate. Some of the samples of your blood and urine will be stored at the University of Manchester and may be provided to other bona-fide researchers working in the field for future research of rheumatoid arthritis and response to treatment. No identifiable data would be stored directly with your sample.

What is genetics?

DNA is a molecule contained within nearly all our body’s cells and it contains genes within it. It is our genes that help to determine certain characteristics, such as hair colour and gender as well as the likelihood that we will develop certain diseases. RNA is a molecule which is responsible for transferring these characteristics from DNA to the rest of our body. Genes vary between people and the purpose of this study is to investigate whether variation in genes affect how people with rheumatoid arthritis respond to treatment with methotrexate. Genetics is the study of genes.

What are the possible disadvantages/risks for taking part?

There are no foreseeable risks for taking part. The study will run alongside your routine rheumatoid arthritis care; it will not influence this process.

What are the possible benefits of taking part?

There is no intended immediate clinical benefit in taking part in this study other then the expected improvement in disease activity seen in daily practice when using methotrexate. However, the information obtained from this study may result in changes in future treatment of patients with rheumatoid arthritis. These changes may also benefit you.
Will the research influence the treatment I receive?

The research does not alter the treatment you receive. Your specialist will start and stop treatments as determined by your clinical condition.

Will my taking part in the study be kept confidential?

We will inform your GP that you are participating in this study by way of a simple letter. Information collected from you will be sent to The University of Manchester. Part of the information will be collected via a computer system. These data will be sent using a secure network system and will be held at the University of Manchester. Your name and any other personal information from which you could be identified will be kept separately from your clinical data. No-one outside the research team will have access to any identifying information and all identifiable information will be stored securely and handled according to the 1998 Data Protection Act.

With your consent, we will share your name, postcode and date of birth with The Health and Social Care Information Centre. The information we share will be used by The Health and Social Care Information Centre and other central UK NHS bodies in order to provide us with information about your health status. This will allow the researchers to be notified of important health events, for example, in the unlikely event you develop a cancer.

The individuals performing the genetic studies will have no access to any personal identifiable information about you apart from your year of birth, your gender, and the information collected during the research about response to treatment with methotrexate. DNA, RNA and the cells and fluids from your blood (called plasma and serum) will be made available to researchers who are undertaking genetic research. The nature of this research is to examine patterns of genes in large numbers of individuals and no results on your own genes will be fed back to you.

What will happen if I don't want to carry on with the study?

If you withdraw from the study, we will destroy all your identifiable samples, but we will need to use the data collected up to your withdrawal.

What will happen to the results of the research study?

Important results of the research study will be published as they become available which may be during the course of the study or after the study has finished, and this could possibly take several years. We intend that any results will be published in established medical journals or will be presented at meetings involved with the field of rheumatology research and these publications will be available upon request from your specialist doctor. You will not be identified in any publication or report.

Who is organising and co-ordinating the study?

The study is being co-ordinated by the Arthritis Research UK Epidemiology Unit at the University of Manchester by Dr. Suzanne Verstappen (Tel: 0161 275 5663; E-mail: suzanne.verstappen@manchester.ac.uk), can be contacted for further details. Results of the study, which are unlikely to be available for at least three years will be sent to your consultant Dr Jennifer Hamilton and Research Nurse Susan Pugmire Tel: 0191 4455191 whom you should contact for information.

Who has reviewed the study?

Before any study can go ahead, it has to be checked by a research ethics committee to make sure that the research is fair. This study has been reviewed and approved by the Central Manchester Research Ethics Committee (MREC no: 08/H1008/25)