

(Hospital headed paper)
PATIENT INFORMATION SHEET

STUDY TITLE: Can clinical, serological, genetic and psychological factors be used to predict response to anti-tumour necrosis factor (TNF) treatment 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.

- **Part 1 tells you the purpose of the study and what will happen to you if you take part.**
- **Part 2 gives you more detailed information about the conduct of the study.**

Part 1

What is the purpose of the study?

When a person is treated with one of the anti-TNF drugs for rheumatoid arthritis, Etanercept, Infliximab or Adalimumab, information is routinely collected to assess whether these new treatments have a greater risk of serious side effects and long term health problems than established treatments. The current study is an extension of this to find out whether clinical, serological, genetic and psychological factors influence arthritis or response to treatment.

Why have I been chosen?

You have been chosen to participate as you are about to start on one of the new treatments called either Etanercept or Infliximab or Adalimumab.

Do I have to take part?

You do not have to take part. If you do decide to take part, you can keep this sheet and will be asked to sign a consent form. You are still free to withdraw at any time without giving a reason. Your participation will not interfere with the standard of care you receive.

What is serology?

Serum is the fluid obtained when blood is separated into its solid and liquid components after it has been allowed to clot. It contains antibodies, which are made by the immune system to defend against infection. Antibodies are thought to play a role in rheumatoid arthritis. Serology is the study of serum.

What is genetics?

DNA (deoxyribonucleic acid) 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. Genes vary between people and the purpose of this study is to investigate whether variation in genes affects how people respond to treatment with Etanercept, Infliximab or Adalimumab. Genetics is the study of genes.

Once a gene is identified, we need to work out how it predisposes to disease. Although DNA is present in all cells, the genes it codes for are not 'switched on' (expressed) in all tissues. It is possible to test whether a gene is expressed by measuring RNA (ribonucleic acid). We think that genes that predispose to rheumatoid arthritis may be expressed in blood cells, because these are important in the immune system. Knowing whether a gene is expressed in blood cells will help us understand how it might predispose to disease.

What will happen to me if I take part?

Your participation will involve the following:

- (i) Agreement to answer questions about your health, feelings towards both your illness and the anti-TNF treatment.
- (ii) Agreement to provide a DNA and RNA sample. This would be obtained from a blood sample, stored and used to investigate genetic factors that may influence arthritis and response to treatment.
- (iii) Agreement to link information already collected from you and from your specialist to the results of the genetic studies.

What do I have to do?

- If you agree to take part in the study, a nurse will ask you to sign a consent form and arrange for a blood test to be carried out. This blood test would be performed as part of the treatment that you would receive anyway, regardless of whether or not you choose to participate in this study, but if you do agree to take part, an additional sample of blood will be taken.
- The nurse will ask you questions about your health and you will be asked to complete a questionnaire about your feelings towards your rheumatoid arthritis and your treatment with Etanercept, Infliximab or Adalimumab.

- At regular intervals over the course of one year, you will be asked similar questions regarding your health and feelings about your disease and treatment. Further blood samples will be taken at these times.

What are the possible benefits of taking part?

We cannot promise that the results of the study will help you but the information we get might help to improve the treatment of people with rheumatoid arthritis.

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?

Yes. All the information about your participation in this study will be kept confidential. The details are included in part 2.

Who is organising and co-ordinating the study?

The study is being co-ordinated by the arthritis research campaign's (**arc**) Epidemiology Unit at the University of Manchester and the lead researcher, Dr Anne Barton, can be contacted for further details. (Tel: 0161 275 5037, Fax: 0161 275 5043, Email: Anne.Barton@manchester.ac.uk)

This completes Part 1 of the information sheet.

If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

Part 2

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

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

Will my taking part in the study be kept confidential?

- Clinical and psychological information about you will be collected and combined with serological and genetic data. 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 Etanercept or Infliximab or Adalimumab, if you participate.
- You will be assigned an anonymized identification number and the results of the genetic tests will be stored on secure databases within the **arc** Epidemiology Unit. Dr. Anne Barton will act as custodian of the samples.

What will happen to the samples I give?

- DNA, RNA and serum will be made available to other researchers who are undertaking research in this field. This will include researchers in other recognised Institutions.
- The nature of this research is to examine patterns of genes and proteins in large numbers of individuals and no results on your own data will be fed back to you.

What will happen to the results of the research study?

Results of these studies will be published in scientific journals and presented at national and international rheumatology / genetics meetings.

Who is organising and funding the research?

The study is being funded from a core programme grant from the Arthritis Research Campaign (**arc**).

Thank you for taking time to read the information sheet, which you should keep for future reference.

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