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PATIENT INFORMATION SHEET

Scottish Early Rheumatoid Arthritis (SERA) inception cohort and biobank

We would like to invite you to take part in this research study. Before you decide whether to take part, you should understand why the research is being done and what it would involve for you. One of the team will go through the information sheet with you and answer any questions you have. Please feel free to talk to others about the study if you wish, and ask us if there is anything that is not clear.

Introduction

Patients with rheumatoid arthritis have inflammation in their joints causing pain, stiffness and difficulty in moving. Sometimes, when patients first see their doctors it can be difficult to tell whether or not they have rheumatoid arthritis. It is also difficult to tell whether their arthritis will be mild or severe in the long term, and which drug therapy would be best for them. Ideally, we would like to have a reliable measurement which would sort this all out. This study will be a national study conducted in rheumatology departments across Scotland.

What is the purpose of this research?

By asking all patients with a new diagnosis of arthritis to take part in the study we hope to build up information about how patients respond to treatment, and how their arthritis progresses. By taking blood to test in the laboratory, we hope that we will be able to identify some changes in the blood that will allow us to predict the course of arthritis better in individual patients and in future this should allow us to provide better treatments.

Why have I been invited to take part?

Because your rheumatologist has recently diagnosed that you are suffering from arthritis.

Do I have to take part?

No. It is up to you to decide whether you want to take part in the study. The standard of your medical care will not be affected whether or not you decide to take part in this study. If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw from the study at any time, without giving a reason. This would not affect the standard of care you receive. Data collected up until then would be used but no further information would be collected. Your participation in the study is unlikely to be of benefit to you but may help in the development of better treatment of arthritis in future. If you do take part in this study, your GP will be informed of your participation.

What will happen to me if I take part?

We will record some personal details, including date of birth, post code, medical history, current treatment, marital status, ethnicity, employment, smoking and alcohol intake. We will keep a note of your CHI number which is your unique personal NHS number. This will allow us to keep track of your health in the future, for instance, when you are discharged following a hospital admission. We will record details of your doctor's examination, blood results, and X-rays. Your personal data will be stored securely on password protected computers and will not be handed on to any external parties, in accordance with the Data Protection Act.

At three clinic visits over the first year, we will ask you to provide a urine sample and some extra blood (up to 20 teaspoonfuls) for analysis of your genes, and the cells and proteins in your blood and urine. At subsequent visits we may ask for an additional donation of blood (up to 10 teaspoonfuls of blood) once a year. If at any stage we remove joint fluid from one of your joints we may need to send some to the lab for routine testing. If there is any fluid left over, it would normally be discarded, but instead we will store it for analysis. We will ask you to provide an extra blood sample (about 4 teaspoonfuls). If you start treatment with TNF inhibitors as part of your routine treatment, we will ask you to provide some extra blood (up to 20

teaspoonfuls) before you start treatment and six months later. All your samples will be stored securely and anonymously, and they will be analysed either now or at some stage in the future. If you have recently had an X-ray of your hands we may be able to use that X-ray for the study, but we may need to repeat this for the purposes of the research study (not for routine care).

Are there any risks to taking part?

Taking blood can lead to some pain and bruising, and occasionally people feel lightheaded when a blood sample is taken. The radiation dose you will receive from the X-rays taken of the hands and feet is equivalent to less than a day's natural background radiation and should be regarded as negligible.

What will happen at each visit to the hospital?

Involvement in this study only requires visits to the clinic every 6 months but you may be asked to come more frequently as part of your routine medical care. At study appointments, we will examine your joints and take a blood sample, to assess the activity of your arthritis. We will ask you to fill in some questionnaires about how your arthritis affects your lifestyle, day-to-day activities and work. The time needed for study procedures should be approximately ten minutes. Visits may last longer as they will, as far as possible, coincide with your usual clinic visits.

What will happen to the samples I give?

The samples will be analysed now, or stored and analysed in the future. The samples will be stored in the Greater Glasgow & Clyde NHS Biobank in Glasgow. We will analyse the cells and proteins in your blood (or urine or joint fluid) and your genes (your DNA) to investigate how your immune system works and how it is regulated. You will not receive the results of any of the tests performed on your blood samples. In the future, we may use your samples in multi-national research projects which may involve transporting your samples abroad.

What may happen in the future?

We are trying to find out more about arthritis, and it may be very helpful to compare your blood samples with those from people who are like you – either friends of the same sex who are about the same age as you, or your relatives. If you are willing, in

the future, we may ask you to deliver a letter to a friend and close relative inviting them to give us the same kind of blood samples we will take from you. It is important that you feel under no obligation to find friends and/or relatives who will help.

If you do not wish to contribute blood and urine samples, you can still help us by giving us permission to extract information from your NHS records now and in the future.

Will I be asked to take part in further research?

We will invite you to join a register so that we can contact you if any research projects are being run that you might be willing to help with. By agreeing to take part in the SERA study you do not commit yourself to being involved in any other projects in the future. You are always free to decline to take part, or to withdraw from any research study at any time without giving a reason.

Travel expenses

You can claim back any extra travel expenses associated with attending the hospital for the research. but if you are attending for other reasons travel expenses are not available through the study.

What should I do if I am not happy with my care?

In the event that something goes wrong and you are harmed as a result of the study, you may have grounds for compensation but you may have to pay your legal costs. There are no special arrangements for compensation in this study, but the normal National Health Service complaints and compensation scheme is available to you.

Private Health Insurance

If you have private medical insurance, you should check with your insurer whether participating in this study will affect your cover.

Who has reviewed this study?

All research in the NHS is looked at by independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed

and given a favourable opinion by the West of Scotland Research Ethics Committee (4).

Who is funding the research?

The research is being funded by a grant from the Chief Scientist's Office, Edinburgh and a drug company called Pfizer (www.pfizer.co.uk).

Can I find out the results of the research?

You can look at our web-site at www.scarnetwork.org for further information.

Who can I speak to if I want further information?

If you would like to speak to another health professional who is not directly involved in the study, please phone Sister Joan Roberts (telephone number 0141 211 3057). If you have any problems, or queries, contact Dr Duncan Porter, (telephone number 0141 211 3262).