The United Kingdom Primary Sjögren's Syndrome Registry

Happy 2009. Some of you may have heard that the UK Sjögren's Interest Group (UKSIG) is organising an exciting new project entitled "the United Kingdom primary Sjögren's Syndrome registry", but what is this project about? When will it begin? Is it relevant to me? Read on and find out more.

What is UK primary Sjögren's Syndrome registry?

The United Kingdom primary Sjogren's syndrome registry (UKPSSR) is a project aims to create a biobank of 500 individuals with Primary Sjogren's syndrome. A biobank is a database of clinical samples (in this case blood) with corresponding relevant clinical data. The ultimate aim of the project is to facilitate high quality clinical and academic research as well as clinical trials of Sjögren's Syndrome.

How can this project help future research and clinical trials of Sjögren's Syndrome?

This project will facilitate research of Sjogren's syndrome in several ways.

Firstly, a major obstacle to the progress in Sjögren's Syndrome research is the difficulty in organising research studies that require the participation of a large number of Sjögren's Syndrome sufferers. Although the number of participants (i.e. the "sample size") needed for individual research projects depend on the research questions as well as other factors, for many clinical studies of Sjögren's Syndrome, a relatively large sample size is required. This is because if the sample size is too small, the data generated from the research may not be representative of all Sjogren's syndrome sufferers. In general, each UK hospital has between 10-70 patients with pSS (primary Sjögren's Syndrome) regularly attending its specialist clinics, this number of patients is insufficient to support most of the clinical trials and observational clinical studies. Therefore, by creating a registry with 500 people with pSS, we will make it easier to organise clinical studies that require a large sample size (e.g. the study of the genetic basis of pSS).

Secondly, it is important to have detailed clinical information of the research participants available for clinical studies so that the data obtained from the research studies can be interpreted in the context of the associated clinical features. However, collecting detailed clinical information is time consuming, expensive and requires considerable support from clinicians and staff of clinical laboratories. Therefore, the creation of the UKPSSR (United Kingdom Primary Sjogren's Syndrome Registry) will not only provide an invaluable resource to support multiple research studies, but also an efficient and economical way of conducting high quality clinical research by pooling and sharing resources.

Furthermore, the UKPSSR will generate invaluable research data from the clinical information that we collect. Finally, the registry will promote collaboration between scientists and doctors in the UK with an interest in Sjögren's Syndrome as well as raising the profile and public awareness of Sjögren's Syndrome.

When will recruitment start and finish?

We are now in the final phase of database development and we plan to start recruiting in the spring of 2009. We expect that it will take between 2-3 years to complete the recruitment process.

What will happen to me if I take part in this project?

If you decided to take part, your consultant (or a member of his/her team) will arrange an outpatient appointment to see you. Depending on the clinic set up of your own hospital, it will either be coincided with your "routine" clinic appointment or a separate appointment. During the appointment, your doctor will assess in detail how "active" is your Sjögren's Syndrome, and how your body has been affected by Sjögren's Syndrome to date (the assessment will include asking questions concerning your health, a physical examination and a blood test). You will also be asked to complete a few questionnaires (which are designed to measure your level of fatigue and quality of life). The questionnaires can be completed at home if you wish and be returned to us using the stamped envelope provided. The appointment will take approximately 30-45 minutes in total.

What happens to the information and samples that I give?

Your clinical data will be entered directly onto the database using secured web-based portals by your doctor. Alternatively, your doctor may send the data to the registry by registered posts. Once we received the data at the registry, our designated senior research nurse will check that there is no missing data or data that have been entered incorrectly. Your blood samples will be processed by a dedicated technical staff in order to extract the serum and genetic materials (DNA and RNA) for storage for future research projects.

What information and clinical samples will be stored in this registry and why?

The following information and clinical samples will be stored.

(1) Clinical data including quality of life assessments.

As mentioned earlier, it is very important to interpret the data generated in clinical studies in the context of the clinical features of individual participants.

(2) The full name, NHS number and date of birth of the participants.

The information will allow us to investigate the longer term health outcome of the participants – e.g. to find out whether Sjögren's Syndrome are linked to other medical conditions; whether people with Sjögren's Syndrome have similar life expectancy to non-Sjögren's sufferers. The information will also allow us to get a better estimate of healthcare resource requirement for Sjögren's Syndrome sufferers.

(3) Blood samples and DNA (genetic materials)

Blood samples and genetic materials are invaluable resources for many clinical studies. For example, these samples are useful for the investigation of the underlying mechanisms that causes

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Sjögren's Syndrome, the development of novel diagnostic tests and other tests for predicting the severity and long-term outcome of Sjögren's Syndrome. Data from these research projects may in turn aid the development of new treatment for Sjögren's Syndrome.

Where will the clinical data and blood samples be stored?

All clinical data will be stored in a central database on a secured, password-protected computer within Newcastle Hospitals NHS Foundation Trust. All identifiable personal information will be stored on separate secured password-protected databases. Any paper copy of your clinical data will be stored in a locked cabinet within the Newcastle Hospitals NHS Foundation Trust. The blood samples and DNA will be stored in a secured laboratory within Newcastle University, who holds a licence for storing human tissue under the Human Tissue Act.

What security measures are in place to safeguard the information and materials of the registry?

Access to the database will require a Username and Password combination. Only the investigators and authorised staff directly involved in this project will have access to the central database and stored blood samples and DNA. In addition, the database will sit securely behind the Newcastle Hospitals NHS Foundation Trust's firewall, preventing unauthorised access. The data on the server will be backed up daily onto the Trust's normal backup medium. The clinical samples are stored in dedicated locked storage vessels in a secured laboratory. The procedure for storage of clinical samples will be in compliance with the Human Tissue Act. All access to the database and stored materials will be logged and audited.

What types of research will be carried out using the information and samples that I give?

Your clinical data and blood samples will be used for both laboratory and clinical research on all aspects of pSS – from finding out what causes pSS, developing better diagnostic tests or tests for predicting the disease severity, to identifying better treatment. We will also use your clinical data to identify suitable candidates for future research and clinical trials. Your samples will not be used in animal research. A list of research projects that will be using the clinical data or samples of the registry will also be posted on our website (www.sjogrensregistry.org.uk) when it goes live in spring 2009.

Who will be using my data or samples for research?

Researchers from both within the UK and abroad can apply to use the data or samples of the registry. We place no restriction on where the researchers are based because we want to encourage the best researchers to use the data/samples of the registry regardless of where the research will be carried out. In order to ensure that the data or samples are used only for high quality research and clinical trials, we will set up a steering committee consisting of scientists, doctors and a patient representative to review all applications for using the data or clinical samples. In addition, identifiable personal information will not be released to third party without prior explicit consent of the participants. Furthermore, all researchers using the information or samples of the registry must provide evidence that they have secured appropriate financial supports and regulatory approvals for their proposed research projects before formal approval will be given. Finally, all researchers using any data/samples of the registry will be bound by written agreements to ensure that the data/samples will be used in accordance with the specified research protocol.

Can anyone suffer from Sjogren's syndrome take part in this project?

No. The term "Sjögren's Syndrome" is often used by doctors to refer to a group of different medical conditions which may have different underlying causes. This project is to create a biobank of individuals with primary Sjögren's Syndrome (pSS) according to the consensus criteria made by the specialists in Sjögren's Syndrome from the US and Europe in 2002.

I am interested in taking part in this project, how can I get involved?

Because the registry requires the collection of detailed clinical information and blood samples using a standardised protocol, all clinical assessments and enrolments will be best carried out by specialists in Sjögren's Syndrome (mainly rheumatologist, ophthalmologists and specialists in oral medicine). Therefore, if you suffer from Sjögren's Syndrome and are interested in taking part in this project, you should discuss with your consultant. Your consultant will be able to tell you whether your hospital is one of the recruitment centres for this project and whether you are eligible. Alternatively, a list of all recruiting hospitals will be posted on the UKPSSR website once recruitment starts. At present, specialists from 24 hospitals across the UK have expressed interests in taking part in recruitment.

If your hospital is not yet one of the recruitment centre but your consultant is willing to carry out the assessment in order for you to take part, you can either ask your consultant to contact us or give us the name of your hospital and consultant so that we can make the necessary arrangement.

Who organise and manage the project?

The project is an initiative of the UKSIG. The investigators for the project are Dr. Wan-Fai Ng (Clinical Senior Lecturer and Honorary Consultant Rheumatologist at Newcastle University and Freeman Hospital), Dr. Simon Bowman (Consultant Rheumatologist at Selly Oak Hospital, Birmingham), Dr. Bridget Griffiths and Dr. Ian Griffiths (both Consultant Rheumatologists at Freeman Hospital, Newcastle upon Tyne). The senior research nurse for the project is Sister Sheryl Mitchell. She is responsible for the management of the database and co-ordination of the data and sample collection. You can find out more about Sheryl in Box 1. There is also a part-time technician (to be appointed) responsible for processing and storing the blood samples.

Who has reviewed and funded the project?

The project has been reviewed by a panel of independent experts and the funding for the project is provided by the Medical Research Council, UK.

How can I find out more information about this project?

For more information, please visit our website or contact Sheryl (Tel: 0191-2448943 or e-mail: Sheryl.Mitchell@nuth.nhs.uk).