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Tracking Parkinson's

(PRoBaND: Parkinson's Repository of Biosamples and Networked Datasets)

Interim Extension

**Patient Information Sheet for:
Patients enrolled in the recent onset cohort of PRoBaND**

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

This study involves people with Parkinson's disease and their relatives and is being conducted across a network of clinics in the United Kingdom. The clinical features of the Parkinson condition will be recorded carefully and repeated over time. Blood samples will be taken for gene tests and for longer term storage to support future research.

Why have I been invited?

You have been invited because you have had a diagnosis of Parkinson's disease and you took part in the Tracking Parkinson's study for a three year period. The present study is an extension to that project. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear or if you would like more information.

As you know, this study involves people with Parkinson's disease and their relatives and is being conducted across a network of clinics in the United Kingdom. The clinical features of the Parkinson condition are being recorded carefully and repeated over time. Blood samples are being taken for gene testing and longer term storage to support future research.

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What is the purpose of the study?

As before, the study is designed to improve our understanding of the mechanisms of Parkinson's disease, in particular to explore variations occurring in the four following areas:

1. Motor features – tremor, stiffness, slowness and poor balance
2. The involvement of memory
3. The degree of improvement with medication
4. The presence of other symptoms including bowel, bladder and blood pressure control.

The extension to the study will continue to involve interviews and scoring on standardised scales to measure the Parkinson features. A blood test will be taken to measure proteins and other markers in the blood as a possible biomarker for Parkinson's.

Information collected will be kept free of personal details according the rules of good clinical practice and data protection. You will be able to keep up-to-date with the study through Parkinson's UK, the study sponsor (who produce newsletters and have a website www.parkinsons.org.uk). In addition the results will be presented at Parkinson's UK research meetings.

What does taking part involve?

If you agree to take part in the study extension, the following assessments will be undertaken:

At the end of the current 3 year study, you will have completed 7 visits, and you will be given information about the study and an information leaflet to review.

6 months after the 3 year study is completed, informed consent will be taken, your medications will be reviewed and your Parkinson's assessed. This will be Visit 8 (42 months).

After another 12 months, a blood sample will be taken for testing for proteins and other possible markers of Parkinson's disease and longer term storage to support other scientific research looking for a marker in the blood stream of Parkinson's disease. Quality of life and depression scores, motor and non-motor symptoms, and any effect that Parkinson's has on your sleep or impulse behaviours and on your bowel habit, and memory will be recorded. This will be Visit 9 (54 months).

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You will therefore have a total of up to two visits during an 18 month period, at 6 months and at 18 months. These visits will usually be combined with your clinic visits. Your visits to the clinic will be longer than a normal clinic visit. The additional scoring that the doctor and nurse will perform will take 10 minutes for the 6 month visit and 60-75 minutes for the 18 month visit. The amount of blood collected will be 30ml (around 2 tablespoons full) at the 18 month visit.

If you choose to take part in the study, some parts of your medical records and the data collected for the study will be looked at by authorised researchers. They may also be looked at by representatives of regulatory authorities and by authorised people from other NHS bodies to check that the study is being carried out correctly. They will all have a duty of confidentiality to you as a research participant and nothing that could reveal your identity will be disclosed outside the research site.

Your General Practitioner will be informed of your participation in the study.

Do I have to take part?

It is up to you to decide. We will describe the study and go through this information sheet, which we will then give to you. You will be asked to sign a consent form to show you have agreed to take part. You are free to withdraw at any time, without giving reason. This would not affect the standard of care you receive or your future treatment.

Who is conducting the research?

The research is being carried out by a group of clinicians in the United Kingdom. The Chief Investigator is Dr Donald Grosset from the Department of Neurology, Southern General Hospital, 1345 Govan Road, Glasgow G51 4TF.

What are the possible benefits of taking part?

It is hoped that by taking part in this research, you will be providing valuable information regarding the nature and progression of Parkinson's disease, and you will be contributing to new research into genetics and biomarkers for the condition.

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Who has reviewed the study?

This study is reviewed by the West of Scotland Research Ethics Committee and the Research and Development Department of NHS Greater Glasgow and Clyde.

What will happen if I develop memory problems related to Parkinson’s disease?

As this is a long-term study, a few patients may experience memory difficulties relating to the Parkinson’s. The research team would like to retain the blood samples and personal data collected during the study, and continue to use it confidentially, both for the P_{RO}BaND research project and for approved research projects in Parkinson’s disease to which the study will contribute. We are therefore seeking your consent to retain the blood samples and personal data for current and further research after the current project has ended, and this would still apply even if you develop memory problems which in the future would limit your capacity to consent to this.

How will you use the blood samples and information collected?

We will use the blood samples and data to answer the research questions in the P_{RO}BaND study as well as future major Parkinson’s disease research studies. This information will not be linked to your name or other identifiers. The samples will be stored in a central laboratory in Cardiff. The genetic information and samples and data may be used in research (relating to diagnosis and treatments) and for teaching purposes by investigators in the UK and around the world.

They will be able to find out a minimal amount of information about the person who gave the sample so that they are able to do useful research, but we will not send them any details that could be traced back to you.

Specifically, we will only send the following information about you with your coded sample: sex, race, year of birth, diagnosis, codes for any other people in your family who gave samples, and relationships of these people to each other. No names, addresses, precise dates of birth, or other information that may personally identify you will be sent.

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We will treat your samples and data as a gift for medication research, and there will be no payment to you for treatments or other medical advances arising from the use of your samples and data.

Who has funded the study?

The study has been funded by the patient’s charity Parkinson’s UK and the future use of the samples and repository will be administered by a committee which will include representatives of Parkinson’s UK and people with Parkinson’s.

What will happen to the results of the study?

We plan to publish any results in scientific journals. Your name would not be mentioned in any publication. We will make regular reports to funding bodies and to patient groups.

What will happen to the clinical information?

The clinical information which concerns your illness and contains your personal details will be kept in your medical records as usual. An anonymised, coded database holding clinical scores and results of your questionnaires and genetic data, without personal details will be held on research computers. This may be used to support other projects which undertake audit and research into Parkinson’s disease. This will allow the best possible use of your information, in a safe way, and without revealing your name or other personal identifiers, to increase our understanding about the mechanisms of the Parkinson’s disease process.

What will happen if there are findings from the study that may need additional medical attention?

You will be informed of these findings, and you will be offered referral to the most appropriate doctor or other healthcare professional to assess this further.

Will I be informed of the results of the blood tests performed in the study?

We will inform you of any results from your blood tests if we think these may be of importance to your future health. With the increasing knowledge about genetics, it is possible that we will find a result in your blood test that should have further assessment, or guide a different treatment approach.

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Will I be contacted in the future about other research?

We would like to retain your name and contact details, as well as your status in the study (i.e. patient with Parkinson’s disease). We would like to have this listing so that we could contact you if there is an additional research project which you might be willing to take part in, at some point in the future. You may still take part in the present study, and advise us that you do not wish to be contacted in future about other research. There is an option box for this, for you to show your preference, on the consent form.

What happens if I choose not to participate?

Participation in the study is voluntary. You are free to withdraw from the study at any time, and if you do decline to take part, this will not affect your current or future treatment in any way.

If you have any further questions?

We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact Professor Keith Muir, Southern General Hospital, 1345 Govan Road, Glasgow G51 4TF, Tel No: 0141 201 1100.

Contacts:

Alison Smith is the Study Co-ordinator, and is based at the Neurology Department, Southern General Hospital, 1345 Govan Road, Glasgow G51 4TF. Tel No: 0141 201 2486. Dr Donald Grosset is the Chief Investigator, and is also based in Glasgow. He can be contacted via Alison Smith.

If you have a complaint about any aspect of the study?

If you are unhappy about any aspect of the study and wish to make a complaint, please contact ~~your~~ researcher in the first instance but the normal NHS complaint mechanisms are also available to you.

Thank you for your time and co-operation.

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