Department of Neurology
Southern General Hospital
1345 Govan Road
Glasgow G51 4TF

Tracking Parkinson's

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

Patient Information Sheet for:
Patients diagnosed with Parkinson's disease in the past 3 years

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 made within the past three years, and we are undertaking a large study in hundreds of patients like you.

What is the purpose of the study?

The study is designed to improve our understanding of the mechanisms of Parkinson's disease, in particular to explore the variations in Parkinson's disease which are known to occur 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.

Formatted: Font: 14 pt
Formatted: Font: Not Bold
Deleted: ¶
Deleted: 1
Deleted: 18/04/11

The study will involve interviews and scoring on standardised scales to measure the Parkinson features and the response to medication. A blood test will be taken and we will look at variation in your genetic and chemical make-up, which might relate to how Parkinson's disease develops, the type of symptoms that you have, and the way in which Parkinson disease affects you. These tests may become useful in diagnosing or treating Parkinson's disease in the future.

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 the study's website (www.proband.org.uk).

In addition the results will be presented at the Parkinson's UK research meeting, and other national and local meetings including patient group meetings. Research updates will appear in the Parkinson's UK newsletter.

What does taking part involve?

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

At the screening visit the clinical features of Parkinson's disease will be recorded, along with family and social history. Past medical history and medication will be recorded.
At the baseline visit, 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 or memory will be recorded. A blood sample will be taken for gene testing for Parkinson's disease and longer term storage to support scientific research looking for a marker in the blood stream of Parkinson's disease.
At the 6 month visit a test of your sense of smell will be performed. Changes in medication and global scoring of your Parkinson's features and an update of your medication will be recorded.
At the 12 month visit, quality of life, a personality score, and environmental exposure questionnaire will be undertaken and the clinician will re-assess your diagnosis.
At the 18 month visit, the questionnaires and observations at the baseline visit will be repeated. A blood test will be taken at this visit.
At the 24 month visit, the observations at the 6 month visit will be repeated and information on the Parkinson's UK Tissue Bank will be given to you for consideration..
At the 30 month visit, the diagnostic features will be reviewed and you will be asked for a decision about donating to the Tissue Bank. A wearing off questionnaire will also be performed.

Deleted: observations and scores at the 12 month visit
Deleted: 1
Deleted: 18/04/11

At the 36 month visit, the observations at the 18 month visit will be repeated. A blood test will be taken at this visit.

You will therefore have a total of 7 visits during the 3 year period, consisting of 2 visits at the beginning, and then every 6 months. These visits will be combined with your usual clinic visits, wherever possible. Your visits to the clinic will however be longer than a normal clinic visit. Taking into account both the questionnaires that you will be asked to fill out, and the additional scoring the doctor and nurse will do, we estimate that the clinic visits will be 60 -75 minutes on each visit. The amount of blood collected will be 60ml (around 4 tablespoons full) on the first occasion, and 30ml (around two tablespoons full) on the second and third occasions, making a total of 120ml over the 3 years.

During the study, if you are taking L-dopa medication for your Parkinson's, a test of your response to this medication will be undertaken on your Visit 5 (24 months) as follows:
You will be asked to omit your medication on the morning of attending the clinic, and a scoring of your Parkinson's motor features will be made. You will then take your usual dose of L-dopa treatment and the response to this will be measured over the next hour. You will then return to taking your medication as normal. If you feel unable for this visit to miss your morning dose of Parkinson's medication before coming up to the hospital, then you can take it at home, come into the hospital, and wait until your second dose of Parkinson's medication is due. We will then score you before and after the second dose of your L-dopa medication.

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.

Deleted: Page Break
Formatted: Left
Deleted:
Deleted: Once d
Deleted:
Deleted: 1
Deleted: 18/04/11

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?

Deleted: Page Break

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.

Who has reviewed the study?

This study has been reviewed by the national research service West of Scotland Research Ethics Committee 1.

Can I receive the result of my gene tests?

No. The tests in this study are performed on a research basis and cannot be used for clinical purposes. The results of the test do not influence the treatment chosen for the management of the condition. In exceptional circumstances, there may be a clinical reason to give you the result of the gene testing, in which case we will make the necessary arrangements.

Deleted: 1

Deleted: 18/04/11

Can outside bodies like insurance companies access the research tests?

No. We will code your sample, and we will not use your name on the specimen, or the recording of the result. The link between the code and your name will be kept confidential.

Coded samples (i.e. without your name) for these tests may be shared with other research groups for analysis. Any information collected during the study will be kept confidential.

We will store the assessment and test results on a secure, confidential database. This will enable us to analyse the information gathered for this research.
When this study is completed we will continue to hold the data on our computer. You may ask for your personal information to be removed from this database at any time, in accordance with the Data Protection Act 1998.

How will you involve my relatives?

We will ask you for information about the ages and health of your parents, brothers and sisters. We will draw a family tree using the information you give us. With your permission we may contact them to invite them to take part in this project. If you prefer we will give you an information sheet similar to this one that you can show to your family yourself. We will only contact your family with your permission.

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 PRoBaND 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.

Deleted: 1

Deleted: 18/04/11

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 PRoBaND 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, with an additional sample stored in European government financed centre in Wiltshire, where your blood cells will be treated to make a cell line which will provide a DNA source which may be used by responsible researchers now and in the future, without having to ask you for more blood samples. 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.

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.

Will I be contacted in the future after completion of the present study?

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 in future if there is an additional research project which you might be willing to take part in, at some point in the future.

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.

Deleted: 1

Deleted: 18/04/11

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 happens if I choose not to participate?

Participation in the study is voluntary. If you decline to take part, this will not affect your current or future treatment in any way.

What happens if I participate but later withdraw from the study?

You are free to withdraw from the study at any time. We would like to keep the data and blood samples you have provided up to the point of withdrawal, but if you would prefer them to be removed from the study, we will of course agree to this. The standard of any future care will not be affected by a decision to withdraw from the study.

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.

Deleted: You are free to withdraw from the study at any time, and

Deleted: if

Deleted: do

Formatted: Font: Bold

Formatted: Font: Not Bold

Deleted: 1

Deleted: 18/04/11

Contacts:

Margaret Crawford is the Study Co-ordinator, and is based at the Neurology Department, Southern General Hospital, 1345 Govan Road, Glasgow G51 4TF. Tel No: 0141 232 7846. Dr Donald Grosset is the Chief Investigator, and is also based in Glasgow. He can be contacted via Margaret Crawford.

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 the researcher in the first instance but the normal NHS complaint mechanisms is also available to you.

Thank-you for your time and co-operation.

Deleted: 1

Deleted: 18/04/11