PARTICIPANT INFORMATION LEAFLET (PATIENTS)

Alterations in Brain Blood Flow in Patients with Parkinson’s Disease
(Is cerebral autoregulation impaired in Idiopathic Parkinson’s Disease?)

You are being invited to take part 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 carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

This is a small research study, which will involve two separate measurements of your blood pressure and blood vessels. The study is being carried by Dr Victoria Haunton as part of a postgraduate educational qualification (MD) with the University of Leicester. The study is being supervised by senior staff from the University of Leicester including Professor Thompson Robinson (Professor of Stroke Medicine), Professor Ronney Panerai (Professor of Physiological Measurement) and Dr Amit Mistri, Senior Lecturer. Dr Nelson Lo, Consultant Physician from University Hospitals of Leicester NHS Trust, is helping to support the research at Leicester General Hospital.

1. What is the purpose of the study?
Blood flow to the brain has to be carefully controlled, otherwise there is a risk of too much or too little blood reaching the brain, both of which may be associated with risk and damage. The ability of the brain to control its blood supply is called autoregulation and it can be scored from ‘0’ (no control) to ‘9’ (perfect control). Certain things affect brain blood flow (autoregulation) including changes in breathing rates and movement. However, at present, we do not know if this control of blood flow in the brain (autoregulation) is affected in patients with Parkinson’s disease and/or whether it is affected by the medicines used to treat Parkinson’s disease. We can measure brain blood flow (autoregulation) non-invasively using ultrasound which detects changes in blood flow in the main brain arteries called the middle cerebral arteries. This research will use these non-invasive measurements of ultrasound to examine brain blood flow changes both at rest and during short periods of breathing manoeuvres and arm movements. This will be done in both healthy volunteers and in patients with Parkinson’s disease whilst on and off their medication. This knowledge will help doctors to better understand the changes in brain blood flow control in Parkinson’s disease.

2. Why have I been chosen?
Measurements in brain blood flow both at rest and during short periods of breathing manoeuvres and arm movements, will be compared between patients with Parkinson’s disease and volunteers of the same age, sex and blood pressure without Parkinson’s disease.
You are being invited to participate in this study as you have Parkinson’s disease.

3. **Do I have to take part?**
   It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You are very welcome to ask questions at any stage of the study. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

4. **What will happen to me if I take part?**
   If you agree to join this study, you will have two study tests on two separate days. Each of these will involve attending the hospital for approximately 2 hours. On the first occasion, you will be asked to take your Parkinson’s medicines as normal on the day of the test. When you attend the hospital, you will be required to discuss this information sheet and sign a consent form. You will then be asked to lie quietly on a bed whilst a small cuff is attached to the fingers of one hand to measure your blood pressure, 3 stickers to your chest to monitor your heart rate, and a small mask over your nose to measure the waste gas from your breathing. You will be asked to wear a head-frame which will hold the small ultrasound probes that are used to measure blood flow against both sides of your head. After the readings have stabilised, 2 recordings will be made, each lasting 5 minutes. This will be followed by a 5 minute recording during which you are first asked to rest for 60 seconds and then breathe in time with a metronome (similar to that used by piano players) for 90 seconds before again resting for 2 minutes. After this, a final recording will be made where, after resting for 90 seconds, the researcher will bend your arm backwards and forwards at the elbow for 1 minute before you again rest for 90 seconds.
   For the second study test, you will be asked to stop your Parkinson’s medicines for between 12 and 24 hours (depending on the type of medicine that you are on) before again attending the hospital for the same set of measurements as before.
   For most patients, this will then be the end of their involvement in the study. However, we may ask a very small group of patients if they would be prepared to have these measurements repeated again every 4 months over the course of 1 year, in order to learn more about the natural history of brain blood flow in Parkinson’s disease. This would mean attending the hospital on 8 occasions rather than 2.

5. **What treatments will be used?**
   No specific treatments are given as part of this small study.

6. **What are the possible disadvantages and risks of taking part?**
   The blood pressure cuff applies only a gentle pressure to your fingers to enable a blood pressure recording to be made every heart beat. This may cause a slight tingling in your fingers, but this should not be painful or cause any harm. Indeed, this type of blood pressure monitoring is often used routinely, e.g. in patients under general anaesthetic or in intensive care.
   The head-frame and ultrasound probes will exert a slight pressure against your head. However, this is not painful, and again is routinely used in many units to monitor blood flow to the brain.
   Over-breathing (hyperventilation) may be associated with symptoms of numbness or tingling in the hands, feet and lips, and a feeling of lightheadedness.
   For the second part of this study, you will be required to temporarily stop your Parkinson’s medications. This will be for between 12 and 24 hours depending on the type of your medicine. Stopping your medicines is likely to make you feel slower, and stiffer and occasionally shakier than normal. In order to try and minimise the effect of this, the study measurement will take place first thing in the morning, so that these symptoms will mostly occur overnight. You will also be asked to bring your medications with you on the day of the second test so that you can take them as soon as the recordings have finished. If, after stopping your medicines you feel
unwell before attending for the test, then you can, and should, take your medications but must notify the researcher that you have done so.

On the day of the study, you will be monitored closely by the researcher (who is a doctor with specialist training in Parkinson’s disease).

7. What are the possible benefits of taking part?
You should not expect to receive any personal benefit from taking part in this study and it is important that you know that the study procedures are not diagnostic, and you will not routinely receive the test results. However, it is hoped that this study will help us all to learn more about Parkinson’s disease.

8. Will travel expenses be paid?
Yes, you will not be out of pocket if you decide to take part in this study. Travel costs to and from the hospital for the study will be reimbursed.

9. What if something goes wrong?
Medical research is covered for mishaps in the same way as for patients undergoing treatment in the National Health Service, i.e. compensation is only available if negligence occurs. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of the study, the normal National Health Service complaints mechanisms should be available to you.

10. Will my taking part be kept confidential?
The blood pressure and blood flow data recorded during the study will be stored on a computer for subsequent analysis. However, you will not be identified by name, and only the researcher will know that the information is related to you. Any information collected during the study will be treated with the usual degree of confidentiality under the data protection act and will not be passed to anyone else without your express permission. Your identity will not be revealed in any publication or presentation of the results from this study. With your permission, your own doctor (your GP) will be notified of your participation in the study.

11. Who is organising and funding the research?
This research is coordinated by Professor Robinson from the University of Leicester.

12. How will I find out the results of the research?
At the end of the study, you will be sent a summary, in plain English, of all of our study findings and conclusions. This can either be posted or emailed to you, depending on your preference.

13. What if I have any concerns?
If you have any concerns or other questions about this study, or the way it has been carried out, you should contact the investigator (Professor Robinson, Telephone 0116 2523182, Facsimile 0116 2525847, Email gtr2@le.ac.uk).
You may also contact the hospital complaints department (Freephone 08081 788337, Facsimile 0116 258 8661, Email pils.complaints.compliments@uhl-tr.nhs.uk).

14. Who has reviewed the study?
The study has been reviewed by the Northampton Research Ethics Committee.

Once again, thank you for taking the time to read this information sheet and for considering taking part in this study.