An EEG investigation of the pain response in Parkinson's disease, and in Healthy Subjects after amino acid modulation

Participant information sheet – Control Participants

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We would like to invite you to take part in our research study. To help you decide, we have provided information on why we are doing the research and what it would involve for you.

• Part 1 tells you the background and purpose of the study and what will happen to you if you take part.

• Part 2 gives you more detailed information about the conduct of the study.

Please take time to read this information carefully, and ask us if there is anything that is not clear, or if you want more information.

PART ONE

What is the purpose of the study?

The purpose of our study is to try and understand why pain is such a common symptom in Parkinson's disease. Although it is not widely recognised, more than 50% of Parkinson's disease patients suffer from chronic pain.

In this study we will also be investigating the response to pain in participants with Parkinson's disease and also Healthy Subjects. We will compare the response to pain between healthy subjects and patients with Parkinson's disease. If we can understand why the response to pain is increased in Parkinson's disease then we hope to be able to develop improved treatments for pain in Parkinson's disease.

Why have I been invited to take part?
We wish to assess the brain response to pain in healthy subjects.

Do I have to take part?
No, it is up to you to decide. We will go through the information sheet with you and give you a copy. If you agree to take part, we will ask you to sign a consent form, and keep a copy for yourself, to show you have agreed this. However, you are free to withdraw from the study at any time.

Where will the study be held?
The study will be conducted by the Human Pain Research Group at Salford Royal NHS Foundation Trust (Hope hospital).

What will the study involve for me?
If you agree to take part in the study you will be required to attend 1 experimental sessions. The session will last approximately 3 hours.

During the session, brief heat pulses from a laser will be delivered to your forearm. You will be asked to rate each impulse on how painful it feels using a 0-10 visual scale. The pain will be tailored to suit you so that the sensations are a mixture of non-painful and moderately painful. You will be in control of the level of pain at all times and the maximum pain sensation will be a little sharp and very brief like oil spitting from a frying pan onto your skin. You will be required to wear safety goggles whilst the laser is in use to protect your eyes.

We will use a procedure called electroencephalography (EEG) to measure the brain's activity. The procedure involves wearing a stretchy cap with electrodes and is entirely safe. You will be asked to have clean hair on the day of the recording and avoid the use of hair conditioning or styling products such as wax, gel or spray. In order to make good contact with your scalp, each electrode will be filled with a salt based gel and we will use a blunt needle to manipulate the gel in the electrode in order to get good contact. The procedure can sometimes be a bit uncomfortable and takes around 20 minutes to complete. The gel will be in your hair throughout the task but we have the facilities for you to wash and dry your hair before you leave.

With your consent, we will inform your GP that you have taken part in the study.

What are the possible disadvantages of taking part?

You may experience some reddening of the skin on your arm at the end of the study due to the laser but this ought to disappear within a few hours to days. There is also a very small risk that you might have some superficial soreness of the skin in which case you will receive some advice before leaving. This area of skin may change in pigmentation but should return to normal within 4-6 weeks. However in more than a decade of our group using this technique one case has been brought to our attention where this pigmentation has persisted.

Will I be compensated for my part in the study?
We will pay £50 per session. This payment includes compensation for travel expenses as well as compensation for the inconvenience of taking part.

What are the possible benefits of taking part?
There will be no direct benefit to you from taking part in the study. The study will help us to understand the causes of pain in Parkinson's disease and hopefully enable us to develop improved treatments for pain in Parkinson's disease.

What if there is a problem?
Any complaint about possible harm you have suffered, or the way you have been dealt with during the study, will be addressed. Details of this are given in part two.

Will my taking part in the study be kept confidential?
Yes. We will follow legal and ethical practice and handle all information about you in confidence. The details are given in part two. With your consent we will inform your GP about the study.

Who is funding the study?
The study is funded by Parkinson's UK.

Where will the results of the study be published?
The results of the study will be published in a PhD thesis and in a scientific journal. When results are available, they will be published on the Parkinson's UK website – www.parkinsons.org.uk.

Who will have access to the study data?
Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the study data to make sure that the research is being carried out appropriately. With your permission, this will include your personal data. Please be assured that anyone accessing your data will have a duty of confidentiality to you as a research participant. Aside from this, data will only be accessed by the research team. The data collected during this study could be used to support research in the future. We may use the anonymous data in future studies or share it with other researchers working on other studies. All of the data used for future research will be anonymised and so no-one will be able to identify you.

PART TWO

What if I don't want to carry on with the study?

If you withdraw from the study, we would normally use any information collected up to this point. We would not use any identifiable information. You can ask us to withdraw your data, however you can only withdraw your data up to 4 weeks after data collection.

What if there is a problem?

Complaints

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact a University Research Practice and Governance Co-ordinator on 0161 275 7583 or 0161 275 8093 or by email to research.complaints@manchester.ac.uk.

Harm

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Will my taking part in the study be kept confidential?

Yes. Information about you that is collected as part of the study will be identified by a unique study number in order to maintain confidentiality. This data which cannot be used to identify you will be stored on a University computer.

Data which can be used to identify you will not be stored apart from the consent form.

What will happen to the results of the study?

Once the study is finished, we plan to publish the results in a medical journal so that others working in the same field will be aware of our findings.

Who is organising and funding the research study?

The study is organised and sponsored by the University of Manchester. The study is being performed as part of a student project.

Who has reviewed the study?

The study has been given a favourable ethical opinion from Greater Manchester West Research Ethics Committee.

Further information and contact details

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