PARTICIPANT INFORMATION SHEET:
Caffeine metabolism in Parkinson's disease
(Non-Parkinson's volunteers)

Thank you for taking the time to read this participant information sheet

You are being invited to take part in a research study being conducted at the Maelor Academic Unit of Medical and Surgical Sciences (MAUMSS), which is part of the Betsi Cadwaladr University Health Board (BCUHB), situated in Ysbyty Wrexham Maelor. Before you make your decision, it is important to explain why this research is being conducted and what it will involve if you decide to participate. Please take as much time as you need to decide whether or not you wish to take part in our study and if you need to, please discuss it with your friends, relatives or your general practitioner. Do not hesitate to ask us if there is anything that is not clear, or if you would like additional information.

What is the purpose of the research study?

Most people consume caffeine on a daily basis in drinks and food, which include coffee, tea, soft drinks, high energy drinks and snacks (chocolate products, some ice creams, chewing gums). Caffeine is made up of many chemicals, which are termed by scientists as biomarkers. These biomarkers can be detected in the blood and urine of people by employing specialist scientific equipment. What we want to do is to look at how caffeine is absorbed in the human body in people with Parkinson's disease (PWP), compared to people without the condition in our research laboratories.

Our aim is to try and establish if and why caffeine is absorbed differently in PWP. In addition, we also want find out if the chemical properties of caffeine change with treatment and the progression of Parkinson's disease. From this research we hope to discover new ways to assist in the diagnosis of this condition, aid in the development of new medications and to improve the management of care for PWP now and in the near future.

Why have I been invited to participate in this study?

We are going to invite people with Parkinson's disease to participate in this study, but we also need to invite people who do not have Parkinson's disease to see if they metabolize (absorb) caffeine differently from them.

Do I have to participate in this study?

No, it is up to you to decide whether you would like to take part or not in this study. To assist you in your decision, we will discuss the reason why we are conducting this study and the commitment you would have to make if you participate in it. If you agree to this, we will give you a copy of this Participant Information Sheet and we will also ask you to sign another form called an Informed Consent Form. We will give you copies of these documents to keep and refer to.

You are free to withdraw from the study at any time without providing us with a reason, by contacting one of the research team listed below. This will not affect your current management of your clinical care in any way, now or in the future.

What will happen to me if I agree to participate in the research?

Your participation in this study will require you to attend the MAUMSS, at a time that will be convenient for you, four times over an 18-month period (First visit, 6, 12, 18 months). On your first visit, we will take your consent to participate in the study and we collect the first set of samples of your blood and urine. The blood sample will be taken by a trained member of the research team, or a trained member of BCUHB staff. The amount of blood we will take from you will be around 10mL, which is equivalent to approximately two teaspoons. We will also ask you to provide about 10-20 mL of your urine sample in a provided container. We will repeat the collection of these samples at 6, 12 and 18 months.

When you attend your first visit after you agree to participate in the study, we will ask you to complete some brief questionnaires about your mood, quality of life and assess your cognition (thinking and memory). This will take approximately five to ten minutes of your time to answer some general medical screening questions, followed by up to 45 minutes to complete the questionnaires and cognitive screen.

The collection of your blood and urine samples, usually takes around 5 – 10 minutes and are similar to the routine hospital procedures. All of your blood and urine samples will be assigned a unique code number, which will only be identifiable to the research team. Your blood and urine samples will be stored securely at the BCUHB MAUMSS Research Centre. This facility houses all of the specialized laboratory equipment and tests that are needed to analyze your blood and urine samples. If you agree to consent to the study, the samples you provide will be kept for the lifetime of the study and then destroyed. Alternatively if you wish, you can consent to gifting any of your surplus blood samples in the current study for use in future research approved by a recognized Research Ethics Committee.

Sometimes blood and urine samples can reveal some abnormal results, which in some instances will mean that we may ask you to repeat these samples for further analysis. In addition, some of your responses from the mood or other questionnaires and the cognitive screen may need further investigation. If these concerns arise, we will firstly discuss them with you and if you agree, we will report the results to your general practitioner.

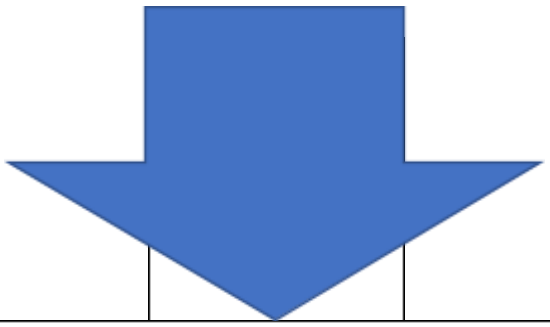
We will also ask you to complete seven-day diary, which you can complete at home to provide us with the consumption of caffeine products you have taken prior to your study visits. We will give you full training and support in completing these diaries.

If you withdraw from the study, you can request for your samples to be disposed of at any time by contacting a member of the research team listed below. Any previously analyzed data, that has been fully de-identified, will remain part of the study.

We will not share any of the data we collect from you with anyone apart from the research team and authorised representatives from Betsi Cadwaladr University Health Board who will check that the research is being conducted properly. All of the data we will collect will be de-identified with a unique code number that only the research team will have access to.

We will also write to your general practitioner to inform them that you will be participating in the study.

To assist you, we have outlined the stages of the study in the figure below.



- Read information sheet and discuss with researcher
- Reflect and ask further questions and think about participating
- Sign informed consent form.
- If you decline, you will have no further involvement in the research

- The researcher will re-confirm your willingness to participate in the study.
- The Researcher will explain what data, blood & urine samples are to be collected from you during the study.
- Researcher will ask you some general medical questions & will ask you to complete some questionnaires on your first visit only.
- Researcher will collect blood & urine samples at your first visit then again at 6, 12 and 18 months.
- The participant will complete a caffeine consumption diary prior to each visit

What will I have to do?

There are no lifestyle restrictions and you can continue your normal activities of daily living if you decide to take part in the study. In addition, there will be no changes made by the research team to your usual health treatments and medications.

Will my expenses be covered?

We will upon request, provide reasonable expense provision for travel and parking expenses for all participants who are not attending routine clinical appointments.

What are the possible risks of taking part in this study?

There are no known significant risks in participation of this study. However, although most people do not suffer any ill effects having a blood sample taken, in some cases there may be a reddening or some irritation of the skin, or some bruising from where the sample is taken from. These can sometimes be painful, but are usually harmless and fade after a few days.

Some people also feel dizzy and faint during and after the test. If this has happened to you in the past, tell the person carrying out the test so they're aware and can help you feel more comfortable.

What are the benefits associated with participation in this research study?

The results of the research will have no direct benefits to you, but the results of this research may benefit PWP in the future, by improving the current methods used to diagnose this condition and assist with the development of new or more personalized treatments.

Unfortunately, we cannot pay you for participating in this study.

What will happen if something goes wrong?

If you feel that you have reason to complain about any aspect of the way you have been approached in the hospital, or the treatment you have received during the course of the study, the normal National Health Service complaints mechanisms are available to you.

You can contact the independent Patients Advice & Liaison Support (PALS) service, at the following hospitals in writing, telephone or by email to the following:

PALS team contact details

Ysbyty Gwynedd Hospital,
Bangor, Gwynedd, LL57 2PW,
By telephone: 03000851234
E-mail: BCU.PALS@wales.nhs.uk

Will my participation in this study be kept confidential?

All the information that we collect about you during the course of our research study will be kept strictly confidential. Any information that leaves the hospital will be coded so you cannot be identified from it. In addition, we will not provide any of your personal information to life insurance, private medical insurance companies or any other third parties.

What will happen with the results generated by this research study?

The findings from our study will be published in scientific journals and presented at conferences in a fully de-identified way. When they are available, the results of the study will be described in a lay format and upon request we will send copied to participants.

Who is organizing and funding this research?

This research has been developed and organized by scientists and clinicians who work for BCUHB. This research study has also been funded with a grant from the Awr Las NHS charity.

Who has reviewed the study?

Our research study has undergone rigorous review by medical clinicians and scientific researchers who work within BCUHB. In addition, this study has been given approval by the XXXXX NHS Research Ethics Committee (Reference) and by the Health Research Authority / Health and Care Research Wales.

How will we use information about you?

Betsi Cadwaladr University Health Board is the sponsor for this study based in the United Kingdom.

We will need to use information from you or from your medical records for this research project.

This information will include your initials, NHS number, name and contact details. People will use this information to do the research, or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we will not be able to let you see or change the data we hold about you.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study. These will be held securely in the BCUHB MAUMSS Research Centre in Wrexham.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- You can find out more about how we use your information
- at www.hra.nhs.uk/information-about-patients/
- at www.hra.nhs.uk/patientdataandresearch/
- by asking one of the research team
- by contacting our Information Governance Department 01978 727689.

By sending an email to Our Data Protection Officer, who you can contact at: bcu.dpo@wales.nhs.uk

Contacts details for the research team:

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