**Acorn Study**

 **Patient Information Sheet.**

**Title:**Brain biomarkers and patient phenotype to identify vulnerability in acute and chronic post-surgical pain and persistent opioid use.

**INVITATION**

You are being invited to take part in a clinical research study carried out at University Hospitals Birmingham. Before you decide whether or notyou wish to take part, you should read the information provided below carefully and if you wish discuss it with your family, friends or GP. Take time to ask questions – do not feel rushed or under any obligation to make a hasty judgement. You should clearly understand the risks and benefits of participating in this study so that you can make a decision that is right for you. You are not obliged to take part in this study and refusal to participate will have no effect on your future care.

**WHAT IS THE PURPOSE OF STUDY?**

We are trying to determine if it is possible to examine a patient's brain activity, mental state, and metabolism before surgery and predict who is more likely to experience greater pain and discomfort and more prone to opioid usage. From these results, we hope to develop a simple test that can warn us about patients who are at high risk of pain and discomfort after a medical procedure.

**WHY HAVE I BEEN CHOSEN?**

You have been invited to participate in the research study because you require surgery.

**DO I HAVE TO TAKE PART? / WHAT WILL HAPPEN IF I DON’T WANT TO CARRY ON IN THE STUDY?**

It is up to you to decide whether or not to take part. If you do decide you will be given this information sheet to keep and will be asked to sign a consent form.

You may change your mind at any time (before the start of the study or even after you have commenced the study) for whatever reason without having to justify your decision and without any negative impact on the care you will receive from the medical staff.

**WHAT DO I HAVE TO DO? AND WHAT WILL HAPPEN TO ME IF I TAKE PART?**

|  |  |
| --- | --- |
| Brainwave testWe will check your brain activity using a test called an electroencephalogram (explained below). For this test, you just need to close your eyes and rest. It takes about 5 minutes. We will collect your EEG once before surgery, and again 72 hours/ after surgery or before you are discharged | QuestionnairesThese forms help us understand your pain and mood before and after surgery. They are different from the questions your surgical care team will ask you. Your answers will not change your treatment. If you need help with the forms, our team is here to help.You will fill out these forms once before surgery, and again 72 hours after surgery or before you leave the hospital. We will also ask you to fill out one more form at 3 months and 6 months after surgery. Additionally, please let us know how much pain you have each week for the first 3 months after surgery using a weblink or SMS or via a telephone call with our team. |
| Laboratory tests |
| Blood testsWe will take a maximum of five tablespoons (70ml) of blood at any time. These will be taken alongside normal bloods where possible. Blood samples will be taken once before surgery and again 72 hours after surgery or before you leave the hospital. | **Urine Samples**We will ask you to give a urine sample before your surgery. **Then, we will send you kits to send us another sample by mail 3 months and 6 months after surgery.** This helps us measure how much pain medicine you are using |

**What is electroencephalography?**



Electroencephalography (EEG) is a technique to record the electrical signals produced by your brain. By placing a cap covered in small electrodes on your head it will be possible to detect tiny electric changes that occur in your brain as it is working away.

**Should you decide to take part, we ask for the following:**

1. **Before the operation:**
* Have one EEG measurement before the surgery, either in the pre-assessment clinic or during your appointment in clinic, or in the operating room
* Complete short series of questionnaires
1. **72 hours after the operation/ Before Discharge:**
* Have one EEG measurement before discharge from hospital
* Complete a short series of questionnaires

With your permission, we will obtain information about how you are recovering from the surgery from the following sources:

• Your medical records specifically pertaining to the surgery held by your hospital;

• Your medical records specifically pertaining to the surgery stored in NHS data centres

**What are the questionnaires?**

The questionnaire we will ask you to fill out are the following:

*The Brief Pain Inventory:* A quick survey to help us understand the severity of any pain you might be experiencing and how it may be affecting your daily life

*The Neuropathic pain Scale*: A quick survey to help us understand the ‘type’ of pain you might be experiencing.

*Hospital Anxiety and Depression scale*: A quick survey for us to assess your mental health depression and anxiety in the hospital setting

*EQ-5D-5L*: A quick survey for us to assess how you are generally wellbeing in daily life.

*The Online Ambiguous Scenarios Task :* This is an online tool that measures how people interpret unclear situations. It presents a series of scenarios that can be understood in different way

* Questionnaires
* Urine sample
* Online Ambiguous Scenarios Task Urine sample
* Online Ambiguous Scenarios Task Urine sample

**Assessment 2: 72 hours after surgery or before you are discharged)**

**Assessment 5: Around 180 days after your operation**

**Assessment 4: Around 90 days after your operation**

**Assessment 3: Weekly reporting of pain levels till 3 months after operation via SMS or phone.**

* Questionnaires
* Urine sample
* Brainwave test
* Blood tests
* Brainwave test
* Blood test

**Assessment 1: Prior to your operation**

**WHAT ARE THE RISKS OR HARMS OF PARTICITPATING IN THIS STUDY?**

Taking part in this study will not cause you any harm. Your treatment will follow the standard care pathway as there is no intervention.

**WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART?**

Whilst there are no immediate benefits to you, you may find it interesting to find out our results and the information gained from this study will help us with future care for patients who have surgery

**WILL THERE BE ANY FINANCIAL REIMBURSEMENTS FOR TAKING PART IN THIS STUDY?**

No financial payments or reimbursements will be received for taking part in this study.

**WHAT IF THERE IS A PROBLEM?**

If you have any concerns about the study you can speak to a member of the research team in the first instance.

If you remain unhappy with their response and wish to make a complaint you can do so by contacting the Patients Advice and Liaison Services via <*insert PALS details – delete text on completing>.*

If you wish to make a complaint about how your information has been handled you can contact the University of Birmingham’s Data Protection Officer via dataprotection@contacts.bham.ac.uk

**WILL MY TAKING PART IN THIS STUDY BE KEPT CONFIDENTIAL?**

We will need to use information from youfrom your medical recordsyour GPHospital for this research project.

This information will include your [initials/ NHS number/ name/ 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 our study’s reference number instead.

All data collected about you during this research will be stored on a password-protected, strictly confidential REDCap database at the University of Birmingham for analysis. You will be assigned an ID code, which will be used in place of your name. Any identifiable information you provide will be stripped and pseudonymized. Collaborators from the University of Birmingham (e.g., doctors, research nurses, physiotherapists, statisticians) will also have access to this data, and members of the Research Ethics Committee (REC) and Health Research Authority (HRA) may need access to ensure the study is conducted in accordance with their approval.

Information retrieved from the questionnaires will be filled directly onto REDCap or from forms and then transcribed onto the REDCap database. These will then be coded and stored only using encrypted computers, complying with data governance laws. Pseudo-anonymised EEG data will be saved on University of Birmingham’s servers. All research members involved with participant data will be bound by the same duty of care and trained appropriately.

The raw data from this study will be retained for up to 10 years after completion on the Birmingham Environment for Academic Research (BEAR) secure server, in line with hospital protocol. Your pseudonymized data may also be shared with students, collaborators of the investigators, and the UK Data Archive.

We will keep all information about you safe and secure. Some of your information will be sent to other international collaborators. They must follow our rules about keeping your information safe.

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 WILL HAPPEN WITH THE RESULTS OF THE STUDY?**

The data may be published in peer reviewed journals and presented at meetings. You will be informed about the publication of results by either letter/email with a free link to the study. No individual will be identified in any publication.

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.

Your data might also be used by other researchers in the future

**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.  If you choose to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop. If you lose capacity to give consent, we will keep information about you that we already have, but will not collect further data.

•    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 data is used for future research this will be only 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.

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We will share your anonymized data with other researchers or institutions outside the UK to help us better understand pain and opioid usage. This could include combining your data with findings from other studies to explore possible new markers for pain or enhance existing research. These researchers will follow strict guidelines to protect your data. Your information will remain anonymous, and you will not be identifiable in any published results or future analysis ,

* **Specialized Expertise**: Access to researchers with unique expertise, techniques, or analytical approaches not available in-house.
* **Advanced Equipment**: Use of high-end or specialized equipment or software that may not be available or affordable locally.
* **Collaborative Insights**: Enabling multidisciplinary collaboration that enriches the analysis with diverse perspectives and methodologies.
* **Data Validation**: Cross-checking results with independent research teams to enhance reliability and objectivity.
* **Resource Efficiency**: Reducing costs and time associated with in-house analysis when outsourcing is more efficient.
* **Broader Comparative Analysis**: Allowing data to be integrated into larger, multi-national studies that require a diverse data pool for broader scientific insights.

 If your data is shared outside the UK, it will be with Academic institutions part of the Wellcome Leap Untangling Addiction ProgramWe will make sure your data is protected. Anyone who accesses your data outside the UK must do what we tell them so that your data has a similar level of protection as it does under UK law. We will make sure your data is safe outside the UK by doing the following

* (some of) the countries your data will be shared with have an adequacy decision in place. This means that we know their laws offer a similar level of protection to data protection laws in the UK
* we use specific contracts approved for use in the UK which give personal data the same level of protection it has in the UK. For further details [visit the Information Commissioner’s Office (ICO) website](https://ico.org.uk/for-organisations/uk-gdpr-guidance-and-resources/international-transfers/)
* we do not allow those who access your data outside the UK to use it for anything other than what our written contract with them says
* we need other organisations to have appropriate security measures to protect your data which are consistent with the data security and confidentiality obligations we have. This includes having appropriate measures to protect your data against accidental loss and unauthorised access, use, changes or sharing
* we have procedures in place to deal with any suspected personal data breach.  We will tell you and applicable regulators when there has been a breach of your personal data when we legally have to. For further details about UK breach reporting rules [visit the Information Commissioner's Office (ICO) website](https://ico.org.uk/for-organisations/report-a-breach)
* [OTHER]

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.

we will keep your study data for a maximum of **10** Years The study data will then be fully anonymized and securely archived or destroyed.

**WHO HAS SPONSORED, INSURED AND FUNDED THIS STUDY?**

This study is sponsored by the University of Birmingham and is funded by the Wellcome Leap.The University of Birmingham has in place Clinical Trials indemnity coverage for this trial which provides cover to the University for harm which comes about through the University’s, or its staff’s, negligence in relation to the design or management of the trial and may alternatively, and at the University’s discretion provide cover for non-negligent harm to participants.

With respect to the conduct of the trial at Site and other clinical care of the patient, responsibility remains with the NHS organisation responsible for the clinical site and is therefore indemnified through NHS Resolution. The University of Birmingham is independent of any pharmaceutical company, and as such it is not covered by the Association of the British Pharmaceutical Industry (ABPI) guidelines for participant compensation. The NHS have a duty of care to participants whether or not the participant is taking part in a clinical trial and the normal NHS complaints mechanisms will still be available to you.

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

You can find out more about how we use your information
•    at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)•    by asking one of the research team by emailing thoracicresearch@uhb.nhs.uk
•    by sending an email dataprotection@contacts.bham.ac.uk

**WHO HAS REVIEWED THIS STUDY?**

This study has been reviewed and given a favourable opinion by the Research Ethics Committee (REC) and Health Research Authority (HRA).

**CONTACT FOR FURTHER INFORMATION**

For additional information now or any future time please contact:

Acorn Central Research Team

Email - thoracicresearch@uhb.nhs.uk

Telephone - 01213714348

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