PATIENT INFORMATION SHEET

One Blo Study: Occipital Nerve Blocks for Acute Treatment of Migraine

IRAS No: 123456

You are being invited to take part in a research study called One Blo. Before you decide, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully.

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.

Why have I been approached about this study?

You are being asked to take part in this research study because you have a bad headache that has not gone away with usual medicines, and additional treatment might help.

What is the purpose of the study?

The purpose of this research study is to see if a fictional drug can treat bad headaches. This fictional drug will put medicine over the nerves in the back of your head.

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. If you decide to take part, you are still free to withdraw at any time and without providing a reason. This will not affect the standard of care you receive.

What is involved in the study?

During the study, we will ask you to describe your headache. We will also ask you how you feel about the treatments. In this study, once you have signed consent, to make sure you are eligible, we will first start with some additional screening procedures (if not already done): pregnancy test, interview, and/or medical chart review. Then, we will apply numbing cream on the back of your head. This step may make the headache go away and may decrease the pain of injection. After 30 minutes, if your headache is gone, or so low that you do not want any more treatment, we will not do any more research treatments. If you still have a headache, we will inject the nerves on the back of your head

with either the fictional drug or saline. Whether you have the fictional drug or not will be decided at random, like the toss of a coin. There is an equal chance that you will receive either study medicine.

We plan to interview some patients who will be selected based on various factors such as whether they agreed or did not agree to participate and what treatment they received. The details of the interview including its purpose will be provided to you as a separate participant information sheet, if you are interested in taking part in the interview. You can take part in the interview even if you decline to participate in the randomised controlled trial, or you can take part only in the randomised controlled trial. For further details, please speak to the researcher who discusses this project with you.

How long will you be in the study?

If you agree to take part, your participation will last about 1 month. You will have to complete 1 in-person study visit and then, when you go home, you will be asked to answer questions and other surveys for 28 days.

What are the study procedures?

Some of the procedures in this study will be repeated several times. The study involvesthe following tests and procedures.

Interviews: A team member will take your medical history, along with a listing of any medications you are taking. Throughout the study, you will be asked to report ifyou think that anything bad has happened as a result of the study.

Medical Record Review: We will review your medical records throughout the study to collect information about your medical history, current health, headache diagnosis, treatments, and medications.

Physical Examination: Exams will be conducted during the study including complete medical and neurological examinations as well as measurements of height, weight, blood pressure, heart rate, and head circumference. These exams will alsoinclude a fundoscopic exam in which we will look at your eyes using different instruments. The light from the instruments used may seem very bright.

Nerve Block Procedure: You will have numbing cream applied to the back of your head. In a clinic room, the study doctor will have you sit on a chair in front of the exam table and lay your forehead on the table. She will apply the cream onto yourscalp under your hair on the back of your head. You can then sit up and move around while the cream takes effect. After 30 minutes, the cream will be wiped off with gauze.

If you still have a headache after 30 minutes, the study doctor will perform occipital nerve blocks. She will have you sit in a chair and put your forehead on the exam table again. She will feel for the bones in the back of your head, and push to find a sore spot, which corresponds to the occipital nerve. She will then inject fictional drug or saline with a small needle over the nerve. She will repeat this on the other side of your head. Each injection will take a few seconds. During that time, you need to hold still, but then you can move around again.

Pregnancy Test (Female subjects only): We will collect urine to complete a pregnancy test. The results will be shared with you and not with your parent(s). If you are found to be pregnant, you will notbe able to participate/continue participating in the study. We encourage you to share the results of a positive pregnancy test with your parents but we cannot make you.

Unbalanced: only potential harms mentioned, no potential benefits mentioned.

What are the risk of taking part?

As with all drugs there are risks of taking them which you need to consider. You need to consider these risks and talk with your doctor about them.

Potential risks associated with Pylarta are:

Potential harms not separated into more serious (or common) and less serious (or common)

- Your headache can get worse
- Balance disorder (increasing the risk of falls and lower body bone fractures)
- Pain, burning, rash and numbness around the injection site
- Nausea
- Heart attack
- Seizures
- Central nervous system disturbances including panic and anxiety
- Respiratory system disturbances including disrupted breathing
- Circulatory system disturbances including palpitations and heart arrhythmia
- **Syncope or passing out**

What are the benefits of taking part?

We cannot guarantee or promise that you will receive any direct benefit by participating in this study.

What are the alternatives?

If you decide not to take part in the study, then you will have the standard of care treatment as advised by your doctor.

What data will be collected and how will you use it?

To safeguard your rights, we will use the minimum personally-identifiable information possible. We will be using information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Pembroke University will keep identifiable information about you for 20 years after the study has finished.

If you withdraw from the study, we will keep the information about you that we have already obtained. We will not collect any further data from you.

Your local health trust will collect information from you and your medical records for this research study in accordance with our instructions. This information will include your name and initials, date of birth, contact details such as telephone number, and medical number.

Your local health trust will use your name, medical number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Pembroke University and regulatory

organisations may look at your medical and research records to check the accuracy of the research study. Your local health trust will pass these details to Pembroke University along with the information collected from you and your medical records. The only people in Pembroke University who will have access to information that identifies you, will be people who need to contact you to process or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, medical number or contact details.

Your local health trust will keep identifiable information about you from this study for 20 years after the study has finished.

Where can you find more information on how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- Looking on the Pembroke University website
- UCL Data Controller contact: data-protection@pembuni.ac.uk

What happens if I change my mind during the study?

You are free to withdraw from the study at any time. You do not have to give a reason and your future treatment and care will not be affected.

What if something goes wrong?

Every care will be taken in the course of this study. If you are not satisfied with the general care and treatment you receive, please speak first to your doctor, who will try to resolve the problem. If you remain dissatisfied and wish to complain formally about the care and treatment received during the study, you may do so under the standard hospital complaints procedure which is available to you from your study doctor's hospital.

To find out about it, ask a member of staff, look on the hospital website or contact the Patient Advice and Liaison Service (PALS).

If you have any problems during the study or would like to discuss the study, you can contact any of the research investigators. You can find their contact details on the last page of this information sheet. In the unlikely event that you come to harm as a result of you taking part in the study, compensation may be available. If you suspect that the injury is the result of the Sponsor (Pembroke University), then you may be able to claim compensation. After discussing with your clinical study doctor, please make the claim in writing to Alex James who is the Chief Investigator for the study and is based at University of Pembroke. The Chief Investigator will then pass the claim to the Sponsor and on to Sponsor's Insurers.

What will happen to the results of the research study?

The results will be published in a respected medical journal once we are sure they are reliable. No information that could identify you will be included and you will not be identified in any report or publication.

This study has been placed on an internet directory of clinical trials (www.clinicaltrials.gov) and the results, once available will be posted here.

Who is organising and funding the research?

ONEBLO is organised by Pembroke University (Lead researcher: Dr Alex James). The research is funded by the Simulated Health Research Council.

Who has reviewed the study?

All research in the health services is reviewed by an independent group of people, called a Research Ethics Committee, to protect participants' safety, rights, wellbeing and dignity. ONEBLO has been reviewed and approved by Hawkins 2 Research Ethics Committee.

What happens now?

You will have some time to think about the study and make your decision. A member of the study team will be happy to answer any questions. You may wish to discuss it with your family or friends. Once you have reached your decision please let the study team know.

You will be asked to sign a consent form and you will be given a copy to keep together with this information sheet. If at any time you have any questions about the study, you should contact a member of the study team or the study doctor.

Contact details

If at any time you have any questions about the study, you should contact your local study team:

Local study team's contact details:

Chief Investigator: Dr Alex James alex.james@pemb.ac.uk

In an emergency it is best to contact your local GP or go to your local casualty department or dial 999 for an ambulance.

Thank you for your interest in our research study