GAP STUDY
GABAPENTIN IN POST SURGERY PAIN

<insert trust logo here>

Participant Information Leaflet

GABAPENTIN IN POST SURGERY PAIN

We are a team of researchers who are conducting a study into alternative treatments for managing pain after surgery. You have been sent this information because you will be having surgery and we would like to invite you to take part in our research study.

Taking part in research is voluntary.

You do not have to take part. If you choose to take part, you are free to withdraw at any time. You do not have to give any reason for your decision. The standard of care you receive will not be affected.

Before you decide whether you would like to take part or not, we would like you to understand why the research study is being done and what it would involve for you. Please read the following information carefully. Talk to others about the study if you wish, such as friends or relatives, and take time to decide. A member of our team will go through this leaflet with you, explain the study in more detail and answer any questions you have. If anything is not clear or you would like more information, do not hesitate to contact us.

What is the purpose of the study?

Gabapentin is a medicine used to treat epilepsy and long-term pain. Recently, doctors have started to use gabapentin to control short-term pain after surgery, with the aim of reducing the amount of other drugs, such as opioids, needed while maintaining good pain relief. Opioid drugs (for example morphine) are the most commonly used drugs to control pain after surgery, but they can cause side effects such as confusion, nausea and slower breathing, which can lead to slower recovery.

With this study, doctors want to find out whether giving patients gabapentin around the time of surgery results in quicker recovery from surgery and fewer side effects from opioid drugs. To investigate this, patients will be given either gabapentin, or an identical looking dummy pill (known as a placebo) in addition to their usual medication. The study will also look into whether using gabapentin as pain relief provides value for money for the NHS.

What will I have to do if I take part?

Consent

You will need to take the time to read and understand what the study would involve for you. You can speak to the research nurses who will answer any questions you may have. If you decide to take part you will be asked to sign a consent form. We hope to enrol 1,500 patients into the study.

Randomisation

We will put everyone who takes part in the study into one of two groups. To try to make

sure the groups are the same to start with, people will be put into a group randomly, so that each person has an equal chance of being in each group. One group will receive gabapentin pills and the other group will receive dummy pills. Neither you, your doctor, nor the research team will know whether you will receive the gabapentin pills, or the dummy pills, and nobody will be able to choose which type of pill you will receive. This is to ensure that the results are not influenced by knowing what treatment you receive. However, your doctor can find out which pill you have received if required, for example, in an emergency.

Treatment

You will be given the study medication in addition to the usual medications; once just before your operation and then twice a day for two days after your operation. Every other aspect of your care will stay the same. We will compare the results from the people taking gabapentin against the results from the people taking dummy pill.

Progress review

We will collect information about your medical history before your surgery and will review your progress until you are discharged home. We will also contact you by phone approximately 4 weeks and 4 months after your operation, to review your progress.

Questionnaires

We will ask you to complete some questionnaires, once before your operation, and approximately 4 weeks and 4 months after your operation. This will give us information about your health; for example, how you are feeling, what activities you are able to perform and how much pain you are feeling.

Hospital visits

You will **not** have to attend any additional hospital visits as part of the study.

What alternatives are there to taking part?

If you decide not to take part in the study, you will receive the usual care provided in your hospital.

What are the possible benefits of taking part?

We cannot promise that the study will help you but we hope that patients who receive gabapentin may have to **take less pain relief**, have **fewer side effects from opioid drugs** and may **recover from surgery more quickly**. The results from this study may help improve the management of pain for other people having surgery in the future.

What are the possible disadvantages and risks of taking part?

The risks of taking part in the study include the risks of side effects from gabapentin (see section below on side effects).

What are the side effects of any treatment received when taking part?

Gabapentin is usually well tolerated and side effects have only been observed in patients who take gabapentin over long periods of time (e.g. to treat epilepsy or long-term pain). It is unlikely that side effects will occur in this study where gabapentin is only taken for a short period of time. The most common side effects include fatigue, drowsiness, dizziness, viral infection, fever and uncontrolled body movements. Side effects of gabapentin are usually short lived and will stop when the medication is stopped. A list of all possible side effects can be found in the Appendix <online>.

What will happen to the study results?

The results will not be known until some time after the last patient has entered the study (about 3 years after the start of the study). You can decide if you would like to receive the study results and whether you would like to know if you received gabapentin or the dummy pill. The results will be reported in medical journals and presented at meetings but your identity will not be disclosed.

Expenses

You will not have to attend any additional hospital visits for this study and therefore we will not be able to refund any travel expenses.

What if there is a problem?

If you have any concerns or questions about this study, please contact the research team listed on Page 5.

If you have concerns about the way you have been treated during the study, you may wish to contact the Patient Advice and Liaison Service (PALS) on:

<Insert local PALS details>

To make a formal complaint, please write to:

<Insert local details>

We have no reason to believe that you will be placed at any greater risk to your health by taking part in this study. However, if something goes wrong and you are harmed during the study there are no special compensation arrangements. If anything goes wrong because of taking part in the study due to clinical negligence, the NHS trust responsible will compensate you.

Will my taking part in the study be kept confidential?

University Hospitals Bristol NHS Foundation Trust is the sponsor for this study based in the United Kingdom. The Clinical Trials and Evaluation Unit, Bristol, on behalf of the sponsor, will act as the coordinating centre for this study. Together we will use 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. Your local hospital will collect information from you and your medical records for this research study in accordance with our instructions. The information collected will be stored in a secure database held on the NHS network at the coordinating centre in Bristol. Paper copies will be held in secure storage for 15 years after the end of the study. Electronic data will be kept indefinitely on a secure database. All information collected about you during the study will be kept strictly confidential.

Your local hospital will collect personal information such as your name, date of birth, address and NHS number, 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 the sponsor organisation, the coordinating centre and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Your local hospital will pass these details to the sponsor and the coordinating centre along with the information collected from you and your medical records. The only people from the sponsor and the coordinating centre who will have access to information that identifies you will be people who need to contact you for follow up 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, address or NHS number. The coordinating centre will store identifiable data such as your name, date of birth, address and NHS number indefinitely in a secure location.

If you give permission, the data collected may be used for future ethically approved studies, but your personal details will not be released.

With your consent, your GP will be informed that you are taking part in the study. Your GP may be asked for information from your records which is required for the study.

You can find out more about how we use your information at http://cteu.bris.ac.uk/privacy-statement/ and www.uhbristol.nhs.uk/about-us/privacy/.

What if new information becomes available

If we get new information about the treatment being studied we will let you know and discuss whether you want to continue in the study.

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

You are free to withdraw from the study at any time you wish without giving a reason and without this decision affecting your rights. You may just want to stop taking the study medication and be happy to continue with the questionnaires so that we can monitor your progress. This will be discussed with you at the time of withdrawal. Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

Who is organising and reviewing the study?

This study has been reviewed by an independent Research Ethics Committee, who protect your safety, rights, wellbeing and dignity. University Hospitals Bristol NHS Foundation Trust is the sponsor and has overall responsibility for the study. The study is coordinated by the Clinical Trials and Evaluation Unit, Bristol. This study is funded by the National Institute for Health Research - Health Technology Assessment Programme (15/101/16).

Further information

It is unlikely that any insurance would be affected by taking part in this study, but you should consider this before consenting and seek advice if necessary.

You can obtain general advice on surgery from:http://www.nhs.uk/conditions/surgery/Pages/Introduction.aspx

You can obtain general information on clinical research from the UK Clinical Research Collaboration who produce a booklet called 'Understanding Clinical Trials' which can be requested by email: crncc.info@nihr.ac.uk or online: http://www.ukcrc.org/public-awareness-of-clinical-research/information-resources-on-clinical-research/

Contact details

Local Principal Investigator

<Insert PI name>
<Insert PI contact details>
<Insert PI contact details>
<Insert PI contact details>
<Insert PI contact details>

Local research team

<Insert coordinator name>
<Insert coordinator contact details>
<Insert coordinator contact details>
<Insert coordinator contact details>
<Insert coordinator contact details>

Coordinating centre

GAP Study Coordinating Centre
Clinical Trials and Evaluation Unit (CTEU)
University of Bristol
Level 7, Zone A, Bristol Royal Infirmary
Upper Maudlin Street, Bristol. BS2 8HW
Tel: <Telephone number>
Email: gap-study@bristol.ac.uk

Thank you for reading this leaflet and considering taking part in our study.

Funded by NIHR