Participant Information Sheet

Patient reported Outcomes, Postoperative pain and Pain relief after daY case surgery

Qualitative Study

Thank you taking part in the POPPY study so far. You are being invited to take part in a further research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish.

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether you wish to take part.

What is the purpose of the study?

You have recently taken part in the POPPY study looking at how people recover from day-case surgery in the short and longer term. In this "qualitative" study we are now asking a much smaller number of people to talk to us in more detail about their experiences before and after surgery. We are interested in their experience of postoperative pain and pain relief. This is to add important detail to the main study, to put the findings in context, and see if we can improve the experience, you had around the time of your operation.

Why have I been invited?

You have been invited to participate in this study because you reported ongoing pain following surgery, and you report that you are still taking pain relief medications. We plan to include 30 participants from the people who took part in the POPPY study.

Do I have to take part?

No. It is up to you to decide whether to take part. You will be asked to go through a consent form before we interview you to confirm that you understand what is involved when taking part in this study. You should ask any questions that you need to or raise anything that concerns you.

You are free to leave the study at any time and without giving a reason.

What will happen to me if I take part?

If you would like to participate in the study, you will be asked to give consent by agreeing to several questions asked by a member of the research team before your interview. You will receive a copy of the consent form. We will then ask you a series of questions about the preparation for your surgery, the recovery you experienced afterwards and your pain management. This will take approximately one hour and take place via video call. This will be on Zoom (Zoom video communications) and will be recorded and stored securely by University Hospitals Plymouth NHS Trust and University of Plymouth. Participants can choose to have their cameras turned off if they wish. The recording will be transcribed and have identifiers removed before analysis and then being deleted.

If we identify a serious problem with your health or pain management, the interview will be paused, and the interviewer will seek attendance of a registered professional member of the research team (a Doctor or Nurse with experience in pain medicine) to complete a risk assessment. Based on this we may ask you to contact your GP or advise you to seek medical attention where we feel it necessary for your wellbeing. We will inform you first if we feel that we need to do this for you.

What do I have to do?

The research team will agree a convenient date and time for your video call. This call will be one-to-one with a member of the research team. They will start by confirming your consent to take part, and they will then ask you a series of questions. The interview will take approximately one hour.

What are the possible disadvantages and risks of taking part?

We are asking you to give details of your experience immediately before and following surgery, and you should be aware that some of these questions may ask you to explain things that you may find difficult or upsetting to talk about. For example, we will ask about the pain you have experienced and any difficult thoughts or challenges you have had.

What are the possible benefits of taking part?

We cannot promise the study will help you but the information we get might help improve the treatment of people with longer-term pain after an operation, or those requiring strong pain killer medications.

Will my taking part in this study be kept confidential?

Yes, all the information about your participation in this study will be kept confidential. If you consent to take part in this study, the records obtained while you are in this study, as well as those related to the POPPY study overall, will always remain strictly confidential.

Your mobile phone number, used for the POPPY study, will be used to contact you to ask if you want to be part of this study. This is held in a secure database (NewcastlePROMS), which only members of the research team can access. The information from this further research study will be held securely at University Hospitals Plymouth NHS Trust (the Research Sponsor) under the provisions of the 2018 Data Protection Act. The video recording will be stored with any identifiers removed. No personal information will be passed to anyone else outside the research team or the sponsor. You will be allocated a unique study number, which will be used as a code to identify you on all study forms.

Your records, with your name removed, will be available to people authorised to work on the study but may also need to be made available to people authorised by the Research Sponsor, which is the organisation responsible for ensuring that the study is carried out correctly. A copy of your consent form will be kept by the Research Sponsor during the study. By signing the consent form you agree to this access for the current study and any further research that may be conducted in relation to it, even if you withdraw from the current study.

In line with Trust policy, at the end of the study, your data will be securely archived for a minimum of 5 years. After this, the data will then be securely destroyed.

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.

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

You can find out more about how we use your information:

- at https://www.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by visiting https://www.plymouthhospitals.nhs.uk/privacy-notice-for-patients-
- by sending an email to informationgovernancepht@nhs.net
- by ringing us on 01752 437284 (Data Protection Officer).

What will happen if I do not want to carry on with the study?

If you decide you do not want to carry on with the study you may withdraw at any time and without giving a reason (although we may ask you for a reason, to help us design better studies for the future, it is up to you whether you are happy to supply a reason or not). A decision to withdraw at any time, or a decision not to take part, will not affect the quality of care you receive. We will keep information about you that we already have.

Will the study information help with other research projects?

It is important that good quality research data can be shared with others to advance clinical research and to benefit patients in the future. After this study, de-identified information collected during the study may be made available to other researchers under an appropriate data sharing agreement, but it will not be possible to identify you personally from any information shared.

What will happen to the results of this clinical study?

The results will produce reports, presentations, and publications. It will not be possible to identify you in any of these. Results of the study will be available on our study website (https://www.raftrainees.org/raft-4-poppy). You will receive a text (or email) message to inform you of this.

Who is organising the study?

Chief Investigator: Dr Mark Rockett, University Hospitals Plymouth NHS Trust.
Research and Audit Federation of Trainees (RAFT).

Who is funding the study?

The National Institute of Academic Anaesthesia (NIAA).
The University Hospitals Plymouth (UHP) NHS Trust Charitable Funds.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the Health Research Authority, the Research Ethics Committee and the Research and Development team at Derriford Hospital.

Further information and contact details

You are encouraged to ask any questions you wish. If you have any questions about the study, please speak to your researcher, who will be able to provide you with up-to-date information. If you wish to read the research on which this study is based, please ask your researcher.

If you have concerns while on the study:

Whilst it is something we hope will not happen, if you have concerns about any aspect of this research, please let us know using the contact details at the end of this information sheet, so that we can address this directly with you.

Alternatively, if you wish to contact the hospital's Patient Advice and Liaison Service (PALS) who offers support, information and assistance, the details are:

Patient Advice & Liaison Service, Level 7
Derriford Hospital
Plymouth
PL6 8DH

01752 439884
plh-tr.PALS@nhs.net

For further information and contact details:

www.raftrainees.org/raft-4-poppy plh-tr.poppystudy.raft@nhs.net

Thank you for taking the time to read this information sheet and to consider this study.