Patient Information Leaflet

Pain and Opioids after Surgery (PANDOS)

We would like to invite you to take part in a research study to help us understand the use of pain relief in the year after surgery.

Before you decide whether you would like 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 – our contact details are at the end of this leaflet. Take time to decide whether you wish to take part. Thank you for reading this.

If you decide that you would like to take part, please tell the person who gave you this leaflet. Or you can contact your local research team using the contact details at the end of this leaflet

What is the purpose of the study?

After surgery, many people are prescribed pain relief medication, but the use of such medication in the year after surgery is not well understood.

In this study, we will investigate people's use of pain relief in the month before they have surgery, while they are in hospital after surgery, and up to one year after they have had surgery. We are specifically interested in pain relievers of the morphine family (sometimes called opioids) and any unwanted effects they may have on people who take them.

This study is taking place in many hospitals across the UK and Europe. We hope that 20,000 people undergoing surgery in the UK will take part, and that many countries across Europe will also take part in the study.

The information that we collect in the study could help us improve patient care in the future.

Why have I been chosen?

Each hospital that is taking part in the study chose a week to take part in the study, this is the hospital's "study week". People who are due to have surgery at that hospital during the "study week" will be invited to join the PANDOS study. You have been invited to take part because you are due to have surgery during your hospital's "study week".

Do I have to take part?

No. It is up to you to decide whether to take part. If you decide to take part, you are still free to withdraw at any time and without giving a reason. If you decide to withdraw at any time, or decide not to take part, this will not affect the standard of care you receive.

What will happen to me if I take part?

If you do decide to take part, we will ask you to sign a consent form. If you take part there will be no extra research visits at the hospital and no change to the surgery or other care that you will receive.

A member of the research team will collect some information from your hospital medical records, and they will ask you some questions, either while you are in hospital or by telephone. If you would prefer to complete the questions online (for example on your phone, laptop or tablet) we can email links to these questionnaires to your email account and you can log in and complete them. The research team will collect data at five time points up till one year after your surgery – these are described below.

- ***Before your surgery***
  The research team will answer any questions about the study and, if you want to take part, they will ask you to sign the consent form.

  The research team will then collect some information from your medical notes (including brief medical history, whether or not you smoke, etc).

  They will ask you questions about any pain that you have and whether you use regular pain relievers. They will also ask you some questions about your quality of life. If you meet the research team in hospital, they will ask you these questions in hospital. They may give you a copy of the questionnaire to take home and complete it and then either post it back or bring it to hospital when you come for your surgery. If you opted to complete the questions online, we will email the link to the questionnaire to your email account. Filling in the questionnaires will take up to 20 minutes and will be quicker if you have no pain.

- ***On the day of your surgery***
  The research team will collect some information from your medical notes about the surgery (including what type of surgery was done and what type of anaesthetic was used). They will not ask you any questions on the day of your surgery.

- ***Approximately 1 week after your surgery***
  The researchers will collect information from your medical notes about any pain relief you had during surgery and while you were in hospital, and any complications that you had following surgery.

  The research team will get in touch with you (by telephone if you have been discharged from hospital, or face-to-face if you are still in hospital). They will ask you questions about any pain that you have and whether you use regular pain relievers. If you opted to complete your questionnaires online, we will email the link to the questionnaire to your email account. Filling in the questionnaire will take up to 20 minutes, and will be quicker if you have no pain.

- ***Approximately 3 months after your surgery***
  The research team will get in touch with you by telephone. They will ask you questions about any pain that you have and whether you use regular pain relievers. If you opted to complete your questionnaires online, we will email the link to the questionnaire to your email account. Filling in the questionnaire will take up to 20 minutes, and will be quicker if you have no pain.

- ***Approximately 12 months after your surgery***
  The research team will get in touch with you by telephone. They will ask you questions about any pain that you have and whether you use regular pain relievers and if you have experienced any problems with the pain relievers you have used. If you opted to complete your questionnaires online, we will email the link to the questionnaire to your email account. Filling in the questionnaire will take up to 20 minutes, and will be quicker if you have no pain.

  If the date of your surgery changes and is no longer in the hospital's "study week" you may still be able to continue in the study and the local study team will get in touch with you to discuss this.

What are the possible disadvantages and risks of taking part?

There are no risks associated with taking part in this study. The study involves the researchers contacting you to collect information as described above – or you completing the questionnaires online. This may be a slight inconvenience for you. The researcher will do their best to arrange these calls at a time that best suits you. If you complete them online you can do them at a time convenient to yourself.

What are the possible benefits of taking part?

It is unlikely that you personally will benefit from this study although the information we get from this study may help us to offer better treatment to patients in the future.

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

You can withdraw from the study at any time without having to give a reason. This will not affect your healthcare or your legal rights. Study information collected up to that point may still be used, but we will not collect any other information about you.

What if something goes wrong?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions – the contact details are at the back of this leaflet. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints mechanisms (or Private Institution). Contact details can be obtained from your local hospital.

Will my taking part in this study be kept confidential?

Yes. All information that is collected about you during the course of the research will be kept strictly confidential. The data collected from the study will be stored on secure University of Aberdeen servers. The University of Aberdeen is the Data Controller for the PANDOS study.

Your name and contact details will be stored in your local hospital and will not be shared outside the hospital unless you sign up to complete the questionnaires by email – in that situation, your contact details (name and email address) will be shared with the University of Aberdeen and stored on secure servers. We will use this information to contact you by email to ask you to complete questionnaires.

All data collected is subject to the UK's data protection laws.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include your name, NHS/CHI number (in the UK), and contact details (telephone number and/or email address). 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 won't be able to let you see or change the data we hold about 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.abdn.ac.uk/about/privacy/ (this is the Data Controllers website) or at www.hra.nhs.uk/information-about-patients/ (which contains information from the NHS Health Research Authority)
- by asking one of the research team
- by sending an email to dpa@abdn.ac.uk, or
- by ringing us on 01224 272596.

What will happen to the results of the research study?

Once the study is finished the data will be collated and analysed before the results can be published. The findings of this research will be published in scientific journals and presented at scientific meetings.

At the end of the study, you will be able to see a summary of the results on the University of Aberdeen PANDOS study website (xxxxxxx).

You will not be identifiable in any publication, presentation or summary of results.

Who is organising and funding the research?

This study is being organised and Sponsored by the University of Aberdeen. The research is being funded by the European Society of Anaesthesiology.

Who has reviewed the study?

This study was reviewed by an NHS Research Ethics Committee, in this case the {Insert REC details}. They have raised no objections to the study. The Research and Development Department of your local hospital has also reviewed and approved the study.

Contact for further information

Professor Patrice Forget (Chief Investigator): email pandos@abdn.ac.uk; telephone 01224 437285
PANDOS study co-ordinator: email pandos@abdn.ac.uk; telephone 01224 438180
At your local hospital:

(Insert local contact details)

Many thanks for taking the time to read this information