Participant Information Leaflet

Supporting Safe Use of Opioid Medication after Surgery

We would like to invite you to take part in a local study looking at supporting patients coming home from surgery with a specific group of medicines, known as opioids. Before you decide to take part, please read the following information carefully.

Why have I been invited?

Your GP practice has agreed to take part in a research study involving the management of opioid medication following a surgical procedure in hospital. We are asking particular patients who meet with the criteria listed below to undertake an **early medication review** with your practice pharmacist.

- Are over the age of **18 years old**.
- Have undergone a **surgical procedure** in Margate, Canterbury, or Ashford and belong to one of the participating GP practices.
- And who were discharged with and continue to take **opioid medicine** to manage their pain.

What is a medication review?

A medication review is a meeting with an expert of medicines, such as a pharmacist, to discuss the benefits versus the risks of taking the medicine, and to suggest safer alternatives where appropriate. This is a **shared decision-making** conversation between yourself and the pharmacist and is led by your own individual needs, preferences, and circumstances.

Why do I need an opioid early medicine review?

Opioids are very strong painkillers that are often given to help with acute pain that can occur after having surgery and often include:

- **Oxycodone** in liquid solution or tablets.
- **Morphine** in liquid solution/capsules/tablets.
- **Codeine** tablets or capsules.
- **Tramadol** tablets or capsules.
- Opioid patches, such as **buprenorphine or fentanyl.**

Opioids are very good at relieving acute pain, such as pain experienced after having a surgical procedure, but opioids can cause **serious health risks** and **side effects**, especially if used for a long period of time (more than 12 weeks). Risks associated with long-term opioid use can include loss of effectiveness (tolerance), experiencing increasingly more intense pain, especially with higher doses (hyperalgesia), dependence on opioids (addiction) and in a few cases an unintentional overdose and/or loss of life. To lower the chance of any of these health risks occurring it is important that you are not using opioids for any longer than you need to once you have left hospital. An early medication review with the pharmacist can help you to achieve this.

What will the early medication review with the pharmacist involve?

The review is completely free of charge, and you will be offered an initial video/phone or in-person appointment, which is expected to take 30 – 45 minutes, this will include:

- Checking that you are eligible to take part in the study and asking you to fill in a participation consent form.
- Collection of some background information about yourself, such as your age, gender, ethnicity, and other medical conditions you may have.
- An initial review of your opioid medication with the pharmacist, where together you will decide if you are ready to stop or lower your opioids and agree on a plan to do this while managing any post-surgical pain.
- Additional follow-up review (15 – 30 minutes) within 14 days of your first appointment.
- It is thought that most participants will need at least one follow-up session with the pharmacist in addition to the initial appointment. The number of appointments needed will depend on how you cope with stopping or lowering your opioid medicine. Extra appointments with the pharmacist can be requested if required.

What happens if I stop taking opioids and my pain comes back?
You may feel some temporary pain when you stop taking opioids. It is likely that this pain can be managed with other medications that have far fewer risks associated with them. The pharmacist may recommend or prescribe additional medication to manage your pain.

Will I suffer any side effects from stopping my medication?
Dose reductions are gradual in order to prevent any withdrawal effects. Although unlikely, you may suffer some temporary side effects such as: sweating, yawning, abdominal cramps, insomnia, restlessness, and anxiety. These are usually only temporary effects and should only last for a few hours/days. Any concerns can be discussed with the pharmacist.

What happens afterwards?
When you stop taking your opioids, appointments with the pharmacist will come to an end. At this point we will ask you to fill in an anonymous questionnaire about your experience. There will be an additional opportunity, should you want to take part, for an online interview with a member of the team or our public volunteers that are supporting this study to discuss your experience in more detail.

What information will be collected about me?
We will need to use information from you for this research project. This information will include your, name, contact details, age, gender, ethnicity, medical conditions, and medications. 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. All data collected about you will be kept completely anonymous and strictly confidential and will be stored securely and in accordance with the Data Protection Act of 1988.

What are your choices about how your information is used?

1. 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.
2. 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

1. at www.hra.nhs.uk/information-about-patients/
2. our leaflet available from **www.hra.nhs.uk/patientdataandresearch**
3. by asking one of the research team
4. by sending an email to descalestudy@kent.ac.uk, or
5. by ringing us on 07734 180792.

Will my family doctor (GP) be informed of my participation in the study?

Your GP practice has agreed to take part in this study. A note will be made by the pharmacist on your medical records to inform your GP practice that you have consented to take part in the study and to record any medication changes agreed after each medication review. Any additional prescription recommendations by the pharmacist will be discussed with and approved by your GP.

What are the benefits of taking part in the study?

The pharmacist will support you with your pain following surgery and ensure that you are not using opioid medicine for longer than is needed or harmful.

What are the disadvantages of taking part in the study?

We do not think there are any disadvantages of taking part in the study apart from the time taken to participate.

Do I have to take part?

You do not have to take part and your medical care will not be affected whether you decide to take part in the study or not.

What will happen if I decide to withdraw from the study?

You are free to withdraw at any point, without giving a reason and without affecting your medical care. If you decide to withdraw any data collected up until that point will be used in the study unless you ask us not to.

Who has reviewed this study?

The study has been approved by North West - Greater Manchester Central Research Ethics Committee.

Who is funding this study?
The NIHR Applied Research Collaboration, Kent Surrey, and Sussex are funding this study.

Who is sponsoring this study?
This study is being sponsored by the University of Kent. If you require any support or guidance regarding this study, please contact: E-mail: ris@kent.ac.uk

Further Information and Contact Details:
If you require any further information, please contact the research team: Email descalestudy@kent.ac.uk or write to:

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Concerns or Complaints:
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