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Analgesia with ibuprofen for patients undergoing elective major Gastro-Intestinal Surgery (PROTECT-AEGIS) Trial

PARTICIPANT INFORMATION SHEET

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Principal Investigator: [insert PI name]

IRAS: 1011239

As part of the PROTECT platform trial, you are being invited to take part in the AEGIS research study, intended to improve the care of patients having an operation involving their gut. Before you decide whether to take part, it is important to understand why this research is being done and what it involves. Please take time to read the following information. Talk to your friends and family about the study if you wish and ask us if anything is unclear.

Why are we doing this research?

Each year, 50,000 patients undergo major gut surgery in the NHS. Pain after major surgery is to be expected but it can be managed through careful use of analgesia. This often leads to longer stays in hospital. Ibuprofen is a very safe and effective pain medicine which you can buy in high street shops. Ibuprofen may help prevent pain after gut surgery, but currently only one in five patients are offered this because some research studies suggest complications of gut surgery (gastric ulcers, poor gut healing and kidney damage) may be more frequent when patients take drugs similar to ibuprofen. Newer research did not have the same results, but doctors remain uncertain about what to do. As a result, patients miss out on the extra pain relief that ibuprofen can provide. We are performing a small feasibility trial, designed to see if patients would be prepared to take part. We will only include you if your surgeon and anaesthetist agree. If we can show that patients and doctors are comfortable taking part in this trial, we will then perform a much larger clinical trial to prove the value of ibuprofen pain relief one way or the other.

Why have I been invited?

You have been invited because you are going to have a type of surgery involving your gut, and this treatment may have a particular benefit in terms of your pain relief that will be required afterwards. Your doctor has also confirmed you can receive ibuprofen following your surgery.

Do I have to take part?

No. It is up to you to decide whether or not you would like to take part in the study. If you decide to take part, you will be asked to sign a consent form. 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. If you decide not to take part, or later to withdraw, this will not affect any part of the care you receive.

What would taking part involve?

After your operation, you will receive one of two study treatments, either standard pain control plus ibuprofen or standard pain control without ibuprofen. You may not know which group you are in, as this will help ensure the study results are fair and unbiased. Standard pain control usually involves morphine-like medicines, and local anaesthetic which can be placed straight into the surgical wound or given through an epidural. Paracetamol is also widely used. This decision will be made at random and neither you nor your doctor will be able to decide which study treatment you receive. If you are in the standard pain control with ibuprofen group, you will be given ibuprofen along with all your usual medications for five days after your surgery. In the standard care group, you will receive the standard pain management for your hospital without ibuprofen. If you are in the ibuprofen arm, you will also receive medication to prevent stomach problems such as Omeprazole or another similar medicine. These medications are widely used but like all medicines, may cause some side effects in some people. These are usually minor and commonly include constipation, diarrhoea, nausea, and vomiting. All of your other treatments will be the same regardless of which study group you are allocated. Your doctors at the hospital are aware that you are in this study and you will be closely monitored throughout your hospital stay. If necessary, adjustments to your treatment will be made to make sure you are safe. We will also let your GP know of your participation in the study so they are aware you might have received ibuprofen during your hospital stay.

We will ask you to answer some questions about your health before and after your operation, which will be online or by telephone if you are at home, and face to face if you are still in hospital. We will record information about any pain you experience on the first five days after your surgery, which will take about two minutes each day. If you have a carer or proxy, they would be welcome to help you answer these questions. The last time we contact you will be 30 days after your operation.

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

If you decide not to take part, or later to withdraw, this will not affect any aspects of the care you receive. You are free to stop taking part at any time without giving a reason. If you choose

to stop taking part in the study, you will remain part of the PROTECT platform, unless you tell us otherwise. We would like to continue collecting information about your health from your medical records and central NHS records. You will not be approached in person for collecting these data. If you do not want this to happen, tell us and we will stop. You can find out what would happen with your data before you agree to take part in the study.

What are the possible benefits of taking part?

You may get better pain relief if you take part in this study, but we don't know this for certain. By allowing us to collect information about the type of painkillers used after your surgery and how you recover, we hope to work out if ibuprofen is helpful for patients recovering from surgery and this may help improve care of patients in the future.

What are the possible disadvantages or risks of taking part?

The possible complications which may occur after gut surgery include gastric ulcers, poor gut healing and kidney damage. These can happen to any patient, and we don't know for certain whether taking ibuprofen for just a few days will increase or decrease this risk. Regardless of which treatment you get, you will be carefully monitored throughout the study to ensure any complications are detected and treated promptly. There will be a small time commitment to answering the questions (approximately two minutes each).

How will my information be used?

You can find out how we will use your information by referring to the relevant sections in the PROTECT Participant Information Sheet.

Who is funding the research?

The study is funded by the NIHR Research for Patient Benefits Programme (NIHR 205324).

What will happen to the results of this study?

Once the study is complete, we will prepare and publish a scientific report. The results will be available to the hospitals that took part in the study. We may share information relating to the study in scientific meetings and it may be published in scientific journals. The results including a plain English summary of the findings will be published on the PROTECT website and you will be able to request a copy by contacting the study team via email: admin@protectresearch.org

Further Information

Further information will also be available on the study website: https://protectresearch.org.

Thank you for taking time to read this information sheet.

Your study doctor is:	
Name:	Contact phone number:
Your research/specialist nurse is:	
Name:	Contact phone number: