Imperial College Healthcare NHS
NHS Trust

Hammersmith & Queen Charlotte's Hospital's
Anaesthetic Department
5th Floor, Ham House
Hammersmith Hospital
London W12 0HS

Ph: HH: 020 8383 3143
QCH: 020 8383 3991
Fax: 020 8383 5373
Email: enda.richardson@imperial.nhs.uk
Website: www.imperial.nhs.uk

Patient Information Sheet

TAP blocks for major gynaecological surgery.

(Formal title: A double blind, randomised controlled trial to assess the efficacy of bilateral transversus abdominis plane blocks for analgesia after major gynaecological surgery.)

You are being invited to take part in a research study. Before you decide whether 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.

Part 1 tells you the purpose of this study and what will happen to you if you take part.

Part 2 gives you more detailed information about the conduct of the study

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

Part 1

• What is the purpose of the study?

In one sentence, the purpose of this study is to find out whether injecting a local anaesthetic into the flanks to block the nerves to the skin over the abdomen (a 'TAP' injection) reduces pain after major gynaecological surgery.

This is a technique of pain control we have been using recently and it sounds sensible, but it's hard to be sure that it really works because there are such big differences in the amount of pain people experience after surgery. What's more, we know that just getting local anaesthetics into the blood stream reduces pain after other surgical operations, so it may be that our TAP injections are working simply because the drug is being absorbed into the blood. This trial is designed to clarify the situation.

• Why have I been invited?

Most patients having major gynaecological surgery are being asked if they would like to take part in our research.

• Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part at all, will not affect the standard of care you receive. If you become unable to give consent during the study, you be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out.

• What will happen to me if I take part?

If you take part, you will be allocated randomly into the 'treatment' group or the 'control' group. In either case you will have an injection on each side of your tummy after you have been anaesthetised for your operation. If you are part of the treatment group, we will leave two thin tubes under your skin alongside the nerves as they pass between the muscles from your vertebral column to the skin. If you are part of the control group, we will leave them just underneath the skin so the local anaesthetic can be absorbed into the blood stream. You won't feel the tubes but you will be able to feel the sticky tape holding them in place. We will infuse local anaesthetics down the tubes over the next three days and in either case you may be more comfortable after the operation than you would have been. We want to see whether it is worth the extra time and effort to get the injections in exactly the right spot.

We will visit you every day for 4 days after the operation and ask you about any pain you may be suffering, whether you have been feeling sick or have any itching, and whether your bowels have got back to normal after the operation. We will also ask you to blow into a small machine that will give us some idea how well your lungs are working and we will make notes based on your medical records (e.g. how much pain killer you require, how much oxygen in your blood). If you don't feel up to doing any of this, we will leave you in peace until the next day. Blood samples will be taken on post-operative days 1 and 2 to measure the levels of lignocaine in your blood and to confirm the safety of the dose of lidocaine used. These will be drawn at the same time of the rest of the blood tests you will require post-operatively. We will also ask you to fill in a quality of recovery questionnaire, which takes less than five minutes to complete, on day 3. After your operation your normal surgical team will look after your care. We do not influence your postoperative management; not the time you're ready to go home, not your post-operative medicines and not your outpatient appointments.

• What do I have to do?

There is nothing for you to do except answer our questions daily ("How much pain are you feeling in your chest? When you breathe deeply? When you cough? Have you been feeling sick? etc."), and blow into a small machine much like the one you will be tested with before the operation as part of our routine preparation for surgery. After the operation we will give you a machine that allows you to give yourself a strong painkiller safely whenever you want it (a PCA machine) and we'll ask you to use it as much as you need to keep yourself comfortable (this is routine practice after major surgery).

Part 2

• What sort of study is this?

You will be entering a randomised trial and we should explain what that is. Sometimes, because we do not know which way of treating patients is best, we need to make comparisons. People will be put into groups and then compared. The groups are selected by a computer which has no information about the individual, so the group a patient is put into is decided by chance. All the subjects in one group then get one treatment, the subjects in the other group get a different treatment and these are compared. Half of our patients will be randomised into the group that gets a TAP injection and half will go into the group that gets a subcutaneous (i.e. under the skin) injection.

This is also a double blind trial. In a blind trial you will not know which treatment group you are in. If the trial is a double blind trial, neither you nor the people looking after you will know in which treatment group you are (although, if your doctor needs to find out he or she can do so). This trial will be double blind because the injections for both groups will be indistinguishable afterwards.

If you are randomised into the TAP block group, your anaesthetist will give you two injections in your flanks while you are under general anaesthetic. He will leave very thin, soft plastic tubes that we can inject down. If you are in the subcutaneous injection group he will inject in the same place but leave the little tubes just under the skin.

• What is the drug or intervention that is being tested?

The local anaesthetic drug we use is called lidocaine. It has been widely used for many years and it has a good safety record. The injection we use to numb the abdomen is called a TAP injection because the nerves we want to numb lie in an area known as the Transversus Abdominis Plane. It is performed while the patient is under general anaesthetic and it involves pushing a needle a couple of inches into the abdominal wall. We use an ultrasound scanner so we can see where the needle is and where we want to put it. It is possible to thread a very fine tube down the needle that can stay in place for several days and allow the local anaesthetic to be injected continuously. TAP injections are often used for pain relief after operations on the abdomen, and we have been using them routinely in this hospital for several years.

• What are the alternatives for diagnosis or treatment?

The usual treatment for pain control after gynaecological surgery is regular paracetamol throughout your hospital stay, morphine for the first few days when the pain is worst, then milder drugs such as tramadol or codeine. Patients in this trial will still have easy access to these painkillers.

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

The local anaesthetic used is usually regarded as a safe drug in the dose we use and no toxicity has been seen in hundreds of patients at this hospital. If you were to develop tingling around the mouth or get a funny metallic taste you should let your doctor or nurse know immediately and the drug can be slowed down. A large overdose might cause you to have a fit.

TAP blocks are widely used and generally regarded as safe, but they are not without risk. The most common complication is that the little tube doesn't end up in quite the right place, but we have had no serious complications associated with their use. Any injection can cause bleeding or introduce infection but, to minimise the risk, the needles are placed with the same sterile precautions that we use for your surgery. However, we have to assume that the TAP injection cannot be quite as safe as no injection or a simple subcutaneous injection.

• What are the possible benefits of taking part?

TAP blocks have been used in gynaecological surgery and seemed to provide pain relief, but they have never been properly assessed. The infusion under the skin is similar to a technique that is known to improve recovery after surgery on the gut, but again it has never been assessed in gynaecological surgery. We cannot promise the study will help you but the information we get might help improve the treatment of other people having operations.

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your research doctor will tell you about it and discuss with you whether you want to continue in the study. If you decide to withdraw your research doctor will make arrangements for your care to continue. If you decide to continue in the study you will be asked to sign an updated consent form. Also, on receiving new information your research doctor might consider it to be in your best interests to withdraw you from the study. He or she will explain the reasons and arrange for your care to continue.

• What happens when the research study stops?

When the study is completed we will write to you to let you know the results.

• What if something goes wrong?

Imperial College Healthcare NHS Trust holds standard NHS Hospital Indemnity and insurance cover with NHS Litigation Authority for NHS Trusts in England, which apply to this study. This does not affect your legal rights to seek compensation.

If you are harmed due to someone's negligence, then you may have grounds for a legal action. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been treated during the course of this study then you should immediately inform the Investigator.

The normal National Health Service complaints mechanisms are also available to you. If you are still not satisfied with the response, you may contact the Imperial AHSC Joint Research Compliance Office.

Complaints statement

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact the study team (contact details at the end of this document) or you may contact the patient advice and liaison team (PALS) on 020 3313 0088 or at pals@imperial.nhs.uk.

• Will my GP know about this?

With your consent, your GP will be told that you have taken part and will have a number to contact us on if he (or she) should wish.

• Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. All data will be stored and analysed on Trust computers. Blood samples will be anonymised before sending to the laboratory and destroyed there after analysis. Data and all appropriate documentation will be stored for a minimum of 5 years after the completion of the study, including the follow-up period. Our procedures for handling, processing, storage and destruction of your data are compliant with the Data Protection Act 1998. It is possible that our study will be audited by a regulatory authority which would require inspection of your medical records to confirm the integrity of our work. Such audit keeps your data confidential.

• What will happen to the results of the research study?

The results of this trial will be published in a medical journal and will also be presented at medical meetings. No individual patients will ever be identified. We will write to you when all the work is complete to let you know our results.

• Who is organising and funding the research?

All the people working on this study are employed by the NHS and no one is being paid specifically for any aspect of their work on this trial.

• Who has reviewed the study?

An official NHS research ethics committee (London Dulwich ref. 16/LO/1250) has approved this study.

• Contact for Further Information

The Chief Investigator for this study is Dr Geoffrey Lockwood, Consultant Anaesthetist at the Hammersmith Hospital. You can contact him by email at g.lockwood@imperial.ac.uk or by phone on 07813 787907.

Even if you decide not to take part, we would like to thank you for reading this far! If you decide to join in, we must ask you to sign a consent form. We will give you a copy of the signed consent form to keep, and this information sheet is also yours.

Imperial College Healthcare NHS Trust

Department of Anaesthesia & Critical Care
Hammersmith & Queen Charlotte's Hospitals
Anaesthesia / Critical Care / Theatres
Specialist Services - CPG 3
5th Floor, Ham House
Hammersmith Hospital
London W12 0HS

Ph: HH: 020 8383 3143
QCH: 020 8383 3991
Fax: 020 8383 5373
Email: g.lockwood@imperialac.uk
Website: www.imperial.nhs.uk

Study Protocol Number: 16HH3332

Ethics number: 16/LO/1250

TAP blocks for analgesia after gynaecological surgery.

Name of Principal Investigator: Dr Geoff Lockwood
(email: g.lockwood@imperial.ac.uk; mobile 07813 787907)

Please initial boxes

1. I confirm that I have read and understand the subject information sheet dated 12/6/16 version 1.0 for the above study and have had the opportunity to ask questions which have been answered fully. ☐
2. I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that if I become unable to give consent during the study, I will be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures will be carried out. ☐
4. I understand that sections of any of my medical notes may be looked at by responsible individuals from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research. ☐
5. I give permission for my GP to be informed of my participation in this study. ☐
6. I understand that all my data (including identifiable data) will be retained and archived securely by Imperial College for 5 years after the completion of the study. ☐

I agree to take part in the above study.

Name of Patient _____ Signature _____ Date _____

Name of Person taking consent (if not the PI) _____ Signature _____ Date _____

Principal Investigator (PI) _____ Signature _____ Date _____

1 copy for patient; 1 copy for Principal Investigator; 1 copy to be kept with hospital notes