Patient Information Sheet

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This is the Patient Information Sheet for a Health Research Study called "ReadyfusOR health economics study"

Pilot healthcare economics and observational study of the One Dose ReadyfusOR (a factory-filled infusion device delivering a continuous infusion of ropivacaine 2mg/ml for up to 48 hours), for the treatment of post-operative pain in patients who have undergone open intra-abdominal surgery (laparotomy).

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REC reference: 17/LO/0572

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Part One

1. Invitation to participate in a research study

You are invited to take part in a clinical study comparing the costs of two forms of local anaesthetic pain relief routinely used after abdominal surgery, namely epidural or wound infusion both used in the UK for decades. As per routine, you and your Consultant Anaesthetist will together agree the best initial post-operative method of pain relief for you, although this can be reviewed, as required. The study is primarily designed to look at the overall costs of the pain relief method you and your doctor agreed.

Before you decide whether to agree to the study, it is important for you to understand why the study is being done and what it will involve. Please take time to read the following information carefully and you will have the opportunity to question your Consultant Anaesthetist, your GP or family and friends. Ask our Research team and/or your Nurse if there is anything that is not clear or if you would like more information on research in general. Take time to decide whether or not you wish to take part. Thank you for reading this information.

2. Why have I been chosen?

You have been chosen to take part in this study because you will be having an abdominal operation, for which local anaesthetic epidural or wound infusion are recommended methods for keeping you comfortable in the first 48 hours after surgery.

3. What is the purpose of the study?

Although managing pain after surgery has steadily improved, there is still a need to identify the best methods after specific types of surgery, based upon effectiveness, reliability, safety, convenience (for both patients and hospital staff) and costs. This study will compare two types of pain management already used routinely in the hospital to see if there are any differences to patient care and costs. We will review pain scores, medication side effects like (sickness or constipation) and ask you and the nursing staff for feedback on your pain relief methods presently used.

There is well-established, high quality evidence to show that both the epidural and wound infusion methods, work well. Unlike previous infusion equipment, the 'ReadyfusOR' is pre-filled in the pharmacy factory and hence simplifies the wound infusion method and reduces the likelihood of error. It is already being used routinely in Germany, and in the UK is now approved for use as part of a "Special Access Programme', while the authorisation for routine availability is being processed by the UK regulators. It contains the local anaesthetic medicine 'ropivacaine', which evidence shows is the safest local anaesthetic we have. The primary aim of this study is to collect health economics data comparing the new 'ReadyfusOR' wound infusion system with epidural pain relief.

4. Do I have to take part?

No. It is up to you to decide whether or not to take part in this study. If you decide to take part you will be given this patient information sheet to keep and be asked to sign a consent form in addition to your normal consent to the operation. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you decide not to take part, or to withdraw from the study at any time, it will not affect the standard of care you receive from any hospital staff.

5. What will happen if I take part?

All of your medical care will be conducted entirely as per routine, including the method of pain management agreed by you and your anaesthetist. You are reading this patient information sheet with a view to considering the invitation to participate in the study. If you are willing to consent to the study, we will ask you to sign a consent form allowing research staff to review your medical records to demonstrate which method of pain relief is more cost effective.

On the day of your surgery, your consultant anaesthetist will discuss the general anaesthetic (being asleep) for the operation, and the combination of ways that pain will be minimised, including the choice between an epidural or 'ReadyfusOR' wound infusion.

In the anaesthetic room, next door to the operating theatre:
1) The epidural method, the anaesthetist will insert a fine cannula (tube) into the epidural space, and a dose of local anaesthetic is injected, before going off to sleep with the general anaesthetic.
2) The 'ReadyfusOR' wound infusion method starts after you have gone off to sleep with the general anaesthetic, when you will have a simple injection of local anaesthetic, called a 'TAP' block on either side of your abdomen, which is commonly used to assist pain relief.

Thereafter, the general anaesthesia and surgery continue identically and as per routine until the time for closure (stitching up) of the wound to complete your operation. Once you return to the ward and wake from your operation your pain relief is provided via the epidural infusion or the 'ReadyfusOR' wound infusion. If your pain levels are not comfortable please tell your Nurse who together with the doctors will review you pain control. As per routine medical care, supplementary pain relieving medicines will be given as necessary.

6. What do I have to do?
As described, once you and your Anaesthetist have decided between epidural or wound infusion, all of your care will follow normal clinical pathways. During the study period, we will collect data about the time and work specifically involved in looking after your pain management. We will also record any side effects or issues requiring extra attention in relation to the pain treatments.

After 48 hours and day five to seven (by telephone if you are home by then), we will ask you a few questions about your experience and views on the pain treatment. All data will be kept in an anonymous paper file, identified by a study code number only, so that your identity is kept confidential, and cannot be traced back to you. We therefore also ask your permission for this anonymised data to be analysed by a group of health economists at Swansea University, who are experts in understanding the health care costs for hospital care, surgery and pain and pain treatments.

Even if you do not wish to complete the questionnaires we would like you to report any side-effects you encounter to the medical team.

7. What are the side effects of treatment?
- Epidural – Medication information sheet available from clinical team.
- Wound infusion – Medication information sheet available from clinical team.

8. What are the possible disadvantages of taking part?
The main disadvantages of taking part in this study are:

- We will require additional contact with you for this research over the phone on day five to seven after your operation.
- The call will be ten to fifteen minutes to check on your pain relief, medication used and any other side effect you may have experienced after leaving the hospital.

9. What if I become, or am likely to become, pregnant or father a child?
Women who are pregnant or are breastfeeding should not receive ReadyfusOR nor should men father a child during the treatment period. It is very important to avoid pregnancy during, and for at least 3 months after treatment, in case the treatment affects the unborn baby. You must therefore use a reliable form of contraception during the trial and for at least 3 month after it has finished. Women taking the contraceptive pill should check with your doctor whether it is all right for you to continue. If you can use it, this is the most reliable form of contraception. It is also a good idea to use a 'barrier' method of contraception, for example condoms or the cap.

If you or your partner does become pregnant during the trial, you will receive counselling from your doctor about the possible risks to you and your unborn baby. A pregnancy test may need to be done before starting this study to rule out the possibility of pregnancy.

10. What are the possible benefits of taking part in the study?
As this study follows two standard care pain control methods, you may not notice a benefit in participation on the study. Although we hope pain control methods may help you recover, this cannot be guaranteed. If you feel too uncomfortable, we will as per routine care, provide whatever additional pain treatments are required to ensure that the pain returns to a tolerable level. The information we get from this study will also help us to improve the choice of treatment for future patients having abdominal operations, for which local anaesthetic epidural or wound infusion are recommended methods for pain management in the first 48 hours after surgery.

Part Two

11. What if new information becomes available?
Sometimes, during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your Doctor will tell you about it and discuss with you how you might be affected.

12. What happens if the research study stops?
This study follows patients having an abdominal operation with local anaesthetic epidural or wound infusion and these are the recommended methods for keeping you comfortable in the first 48 hours after surgery. The research team will stop the research after twenty patients are enrolled, with ten in each treatment group. Once the study treatment is completed, after 48 hours, you will continue to be followed up and receive conventional therapies and be offered treatments that become available if they are appropriate.

13. What if something goes wrong?
Every care will be taken in the course of this study and the treatment methods are normal care for abdominal operation, however if you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about any aspect of the way you have been approached or treated during the course of this study, you should ask to speak to the research team at The London Clinic, Advanced Therapies Centre who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by calling the Clinical Trials Manager on 0203 219 3570. Details can be obtained from The London Clinic website on feedback and complaint process.
http://www.thelondonclinic.co.uk/patient-care/feedback.

We are keen to hear your views about the Clinic and to listen to feedback, whether it is positive or negative. If you would like to comment formally, please contact:
Patient Experience Manager, The London Clinic, 20 Devonshire Place London, W1G 6BW, and by email at patientexperience@thelondonclinic.co.uk

14. Will my participation in the study be kept confidential?
If you consent to take part in the research, all information which is collected about you during the course of the study, will be kept strictly confidential. The information collected will be primarily to do with the treatment you receive, the side effects that you may or may not have had whilst receiving

treatment. You will be allocated a unique study number, which will be used to anonymise all your personal data.
With your permission, The Advanced Therapies Centre will hold your name, telephone number postal and email address for the purpose of follow up call at 5-7 days post operation. The questionnaire data will be stored securely The London Clinic and on paper and electronically and will only be accessible by authorised personnel. Identifiable data will not be used for any other purpose. A copy of the consent form you sign will also be kept by the investigators so they can confirm that your consent was given to join the trial. In order to check that the information sent to them is accurate, and that the study is being carried out properly, staff from the hospital or the regulatory authorities may wish to see your medical records. We will inform your GP (and other doctors treating you for other medical conditions) of your participation in the study.

15. What will happen to the results of the research study?
We plan to publish the results of this study in a scientific journal so that the information will be available all. We will post copies of all study publications on our The London Clinic website. All clinical trials results are require a summary of results and this will be published in due course on http://www.isrctn.com/. You will not be mentioned personally in any report or publication. Please contact the ATC team (contact details on Page 7) if you require a copy of the publication.

16. Who is organising and funding the research?
The study is organised by staff at The London Clinic, with Professor Richard Langford as the Chief Investigator. The study has been funded by BioQ Pharma Incorporated. Your doctor is not being paid for including you in this study but the hospital is paid for research and activity outside your normal clinical care.

17. Who has reviewed the study?
All research in The London Clinic is looked at by independent group of people, called an Ethics and Research Governance Committee, to protect your interests and the hospital reputation. This study has been reviewed and given favourable opinion by a UK National, Research Ethics Committee. The details are on the cover page of this document. In addition the Advanced Therapies Centre and London Clinic Pain service for the hospital.

18. Health Insurance.
All private patients with treatment covered by insurance company will need to inform them of your participation on the study. You and your insurance company will not be required to fund any additional care outside standard care. The Sponsor of the research will cover all additional care as part of the research.

19. Contacts for further information

As you will be in the hospital throughout the study treatment period, you should initially speak to your nurse and Clinical trial coordinator, if you have any concerns, and if these or questions relate to this study, you and/or your nurse should please contact your local study team.

If after your discharge, you have a study related question, please telephone the Advanced Therapy Centre staff at The London Clinic on 0203 219 3570 who will be able to assist you, Monday to Friday 09.00h to 17.00h. For Out of Office hours please contact the 24-hour Emergency Telephone Number: 0207 935 4444 and ask for "Matron's Office or on call Doctor for ATC_ 047 ReadyfusOR health economics study".

In the event of an emergency please visit your nearest hospital or GP without delay providing them with above details if necessary.

Principal Investigator:
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If you wish to contact the research team, then the contact details are:

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The London Clinic
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1 Park Square West,
London NW1 4LJ
Email: ATC@thelondonclinic.co.uk
Phone: 020 3219 3570
Mobile: 07714396278
Thank you for taking the time to read this information leaflet.