PATIENT INFORMATION SHEET

Pain Relief in Major Amputation (PRIMA): A randomised clinical trial comparing pre-incision 'single-shot' nerve block and continuous peri-neural catheter for those undergoing a major lower limb amputation

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the information carefully and ask us if there is anything that is not clear or if you would like more information. The Sponsor of this study is the Newcastle-upon-Tyne Teaching Hospitals.

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Local Patient liaison service contact details: For independent advice on research, you can contact PALS (Patient Advice and Liaison Service) on free phone **0800 0320202,** Text/sms**: 0781 5500015**, email **northoftynepals@nhct.nhs.uk** or by post: **Freepost PALS: RLTC-SGHH-EGXJ**

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PART 1

1.0 What is the purpose of the study?

Currently we offer two types of pain control around the time of amputation that are the current standard care and not experimental. Both perform well but we do not know if one is better than the other for controlling pain at the time of amputation surgery and into the longer-term.

One is a single injection around the nerve, with a pain control drip into the vein, that you can control by a button (PCA). The other is a small tube inserted around the nerve which allows the continuous drip of pain control medication around the nerve for about seven days.

We hope to find out which is better (if any) by comparing the two types of pain control. We do not know which is the 'gold' standard and hope this trial can help inform care for many patients in the future, to improve their experience, pain and recovery. This study will help inform practice across the UK.

1.1 Why have I been invited?

You have been invited to take part because you are going to have an amputation of the lower limb. We hope to provide one of the two licenced types of pain control for you. With your involvement we aim to find out if one type is better than the other, we do not know at present.

1.2 Do I have to take part?

Your participation in the PRIMA study is entirely voluntary.

It is up to you to decide whether or not to take part. You can discuss your participation in the trial with your family, friends or GP. If you do decide to take part you will be asked to sign a consent form, a copy of which will also be given to you to keep. If you decide to take part, 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. The standard of care you receive will not be affected and you will receive one of the two pain control methods, but not as part of the study.

1.3 What will happen to me if I take part?

The study is being carried out by a team of surgeons and anaesthetists, called the PRIMA group. The study group will collect data regarding your health, procedure you undergo and the recovery period afterwards. We are most interested in the pain you experience around the time of surgery and over the course of your admission. If you agree to take part, we will randomly (at the roll of a dice or by chance), give you to one of the two methods of pain control, a single injection around the nerve to the leg or a continuous drip for seven days. Both of these are currently standard care, but it may be that one is better than the other.

The study will not alter the other aspects of the care you receive but will allow us to understand if there is a difference in how well these pain control methods work. All data will be anonymised.

If you agree to take part the following will happen to you:

At the start: We will collect details about you (age, sex, weight, height), the surgery you are having and your pain level before the surgery. We will need to use information from you and from your medical records for this research project. This information will include your [initials/ NHS number/ name/ contact details). People will use this information to do the research or to check your records to make sure that the research is being done properly. We will keep all information about you safe and secure.

i. We will ask you to complete a questionnaire about your quality of life and your pain so that we can understand any pain that you are experiencing.

ii. You will randomly (by chance or rolling of the dice) to receive one of two pain control methods (single shot injection and a pain control button through the vein compared to a continuous drip into nerve itself).

iii. ***Afterwards:*** We will then observe your recovery, ask you to record your pain daily over seven days on a pain chart. We will also record any additional pain control/tablets that you require or any further procedures that you undergo.

Once you leave hospital: We will also see you back in the clinic as per routine care but also as you some questions regarding pain control, the level of pain and the effect on your quality of life by using a questionnaire.

iv. ***In about a year:*** We hope to gain funding so that we may contact you over the long-term (in one year) to see how your recovery has been and whether you experienced any more long-term pain.

1.4 What will I have to do?

If you take part in this study, you will be asked to fill out some questions on your pain as listed above. After your surgery you will be asked complete a daily pain score and at day seven you will be asked to complete a pain related questionnaire. We will repeat this at your routine follow-up visit to the out-patient department at around 6 weeks after your operation. If we can, we would like to contact you in a year to discuss your pain (if any) and your progress.

1.5 What are the possible disadvantages and risks of taking part?

At present we do not know which pain control method works better. One possible disadvantage is that after the study is completed and we compare the results, you may have received one pain control method that does not work as well as the other. At the moment we do not know, the only way to find out is to compare these in a study.

Both types of pain control are used routinely at present and are licenced, safe methods of pain control. Therefore, the risks of unexpected problems are low. The specific risks of either pain control types are: bleeding (less than 1%), infection (less than 1%), failure (less than 5%) and injury to nerves or permanent alteration of feeling (less than 1%). These apply whether or not you choose to take part in the study.

1.6 What are the possible benefits of taking part?

The information from this trial will be useful to improve the overall quality of care that we will provide for the future patients undergoing an amputation. The results are likely to improve care both in the local area but also nationally.

1.7 What happens when the study stops?

When this study is stopped, you will no longer need to undergo any study-related follow-up. You will continue your usual just as before you enrolled in this study.

1.8 What if there is a problem?

The research study team (PRIMA Group) will be carefully reviewing your progress to ensure that there is no harm or ill effect throughout the study. We know that these interventions are safe, with low risks, and are used daily in many hospitals. If a side effect, or harm were to occur, we will aim to find this out early, and attempt to remedy these promptly. We ask you to please feed back to us at any point if you have questions or concerns.

As an aside in the unlikely event of a complaint about the way you have been dealt with during the trial or any possible harm you might suffer will be addressed carefully, you are encouraged to raise any concerns as we can learn from these. The detailed information on this is given in Part 2.

1.9 who has reviewed the study?

All research in the NHS is looked at by an independent group of people called an NHS Research Ethics Committee (REC). This is to protect your interests and safety. This study has been reviewed and given a favourable opinion by : The South-East of Scotland Research Ethics Committee on the 17th of February 2021 (REC ref: 21/SS/0013)

1.10 Will my taking part in the trial be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

1.11 Will my GP be informed?

If you decide to take part in this study and consent to have your GP informed, then we will inform your GP. Your participation in the study will also be noted in your medical records

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision

PART 2

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

You can withdraw at any point without the need to give us a reason as to why you chose to withdraw. If you lose your capacity to provide consent for inclusion in this study, we will withdraw your participation. If you withdraw from the study, you will still undergo standard NHS care. Information which has been collected will not be used.

2.1 What if there is a problem?

Complaints

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. If you remain unhappy and wish to complain formally, you can do this through contacting the sponsor of the trial. For independent advice on research, you can contact PALS (Patient Advice and Liaison Service), details are on the front page of this leaflet.

Harm

It is very unlikely that you will be harmed by taking part in this research study, we carefully monitor you and are always available to raise and concerns, both the study PRIMA team or the care team looking after you on the ward are available to ask or alert to any issues.

However, if you wish to complain or have any concerns about the way you have been approached or treated in connection with the study, you should ask to speak to the chief investigator who will do their best to answer your questions. If you remain unhappy and wish to address your concerns or complaints on a formal basis, you should contact Patient Information & Liaison Service, and we welcome feedback to improve our practice and care. The details are on the front page of this information sheet.

2.2 Will my taking part in this trial be kept confidential?

Information relevant to your medical condition will be collected as part of this study. All information regarding your medical records will be treated as strictly confidential and will only be used for medical research. Your medical records may be inspected by competent authorities and properly authorized persons, but if any information is released outside the study office this will be done so in a coded form with your name and other identification criteria replaced by a code in order to make it impossible or at least very hard to identify the person in question.

Anonymised data will be stored on a secured computer database for a minimum of fifteen years. It will then be disposed of securely. If you decide you want to take part, you will also be asked if you would like to potentially be contacted to discuss your experience of taking part in the study in the future. This is entirely optional and not wanting to be contacted will not stop you from being in the study. If you do agree to being contacted in the future, you will be asked to give some personal details (e.g. telephone number, address or email address) which will be used to contact you again. This information (i.e. contact details) will be kept with your consent form in the study site file at the hospital. Your information will not be shared with anyone else and will be archived for 15 years in a safe/locked NHS office. The study team, or Newcastle research department, NHS research and development departments or regulatory authorities may have to look at medical notes or research data as part of monitoring and audit processes dictated by law. 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. The Sponsor will store informed consent forms after completion of the study in a locked safe space adhering to NHS research practices and a period of 15 years, after which all relevant information will be safely destroyed. All information and study forms will be handled according to the Data Protection Act.

2.3 Will any genetic tests be done?

No genetic testing will be performed at any point.

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

The results of this research will be published and presented at scientific meetings when the study has ended. Published reports will not include your name or any other information that would identify you. You have the right to be informed of the overall results of this study. If you wish to find about how the study is going or the results please let me (the chief investigator, Sandip Nandhra) know.

2.5 Who is organising and funding the research?

The Sponsor is Newcastle-Upon-Tyne Hospitals Joint Research Office with overall responsibility for the study and study oversight. The study is organized and run by the Chief Investigator, Mr Sandip Nandhra, and the co-investigators listed above. The study is funded by a competitive grant received from the Royal College of Surgeons of Edinburgh.

2.6 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.hra.nhs.uk/information-about-patients/
- by asking one of the research team
- by sending an email to R&D Enquiries, or
- by ringing us via the Vascular research office.

Further, a Data Protection Officer ensures that individual rights are respected and that we (the Sponsor and research team) comply with the law. If you have any concerns or questions about how we look after your personal information, please contact the Data Protection Officer.

Thank you for taking time to consider participating in the study. If you agree to take part you will be given a copy of this information sheet and a copy of the signed consent form.

You can find all relevant contact details on the 1st page of this information sheet.