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A Randomised Controlled Trial to investigate the effectiveness of ThOracic Epidural and Paravertebral Blockade In reducing Chronic Post- Thoracotomy Pain: 2 (TOPIC 2)

Patient Information Sheet

Summary of TOPIC 2 study

- We would like to invite you to take part in the TOPIC 2 study.
- The study is comparing *2 recognised and safe anaesthetic* techniques which are widely used.
- We are trying to investigate whether one technique may reduce long term pain following surgery.
- Joining the study is voluntary and your participation should be freely given but before you decide, we would like to provide you with information about why the research is being done and what it will involve.
- Please take time to read this information sheet fully. It will provide you with information about the study and what will happen to you if you wish to take part.
- You will have the opportunity to discuss the study with a member of the research team and there will be time to ask any questions you may have.
- Please feel free to talk to others about the study if you wish.
- The study title has been shortened and will be referred to as the TOPIC 2 study.

Why have I been invited?

You are invited to participate in this study as you are going to have planned chest surgery (Thoracotomy). As part of your anaesthetic you will also receive pain relief. This will be either paravertebral blockade which is an injection to the back covering one side of the chest or thoracic epidural blockade, an injection to the back, covering both sides of the chest. Both are standard techniques and are widely used in this type of surgery.

This study will recruit 1026 patients from approximately 25 UK hospitals. Patients who choose not to participate will receive whichever procedure is currently used in the hospital performing the surgery but there is uncertainty about which procedure is best. Finding out which is the best is what the study is trying to find out.

What would taking part involve?

Topic 2 study aims to compare two pain relief procedures during an operation called a thoracotomy and to see whether either technique can reduce long term (Chronic) pain. All patients who undergo surgery to the lung will require some type of pain relief as part of their anaesthetic during the operation and a minority of patients will go on to experience chronic pain.

We are assessing whether the use of paravertebral blockade, anaesthetic injection to the back covering *one* side of the chest at the time of surgery will reduce long term pain in comparison to thoracic epidural blockade anaesthetic injection to the back, covering *both* sides of the chest.

By the end of this study we hope to better understand how the method of anaesthetic pain relief affects long term pain. This understanding of chronic pain is the primary goal of this research.

Both types of anaesthetic pain relief are commonly used, but it is not known which type is better at reducing long term pain after surgery. If this study is successful it will help many future patients.

If you agree to participate in TOPIC 2, you will be randomised to one of the two widely used techniques described. Randomisation is a method based on chance by which study participants are assigned to a treatment group. You will either receive Paravertebral Blockade OR Thoracic Epidural Blockade.

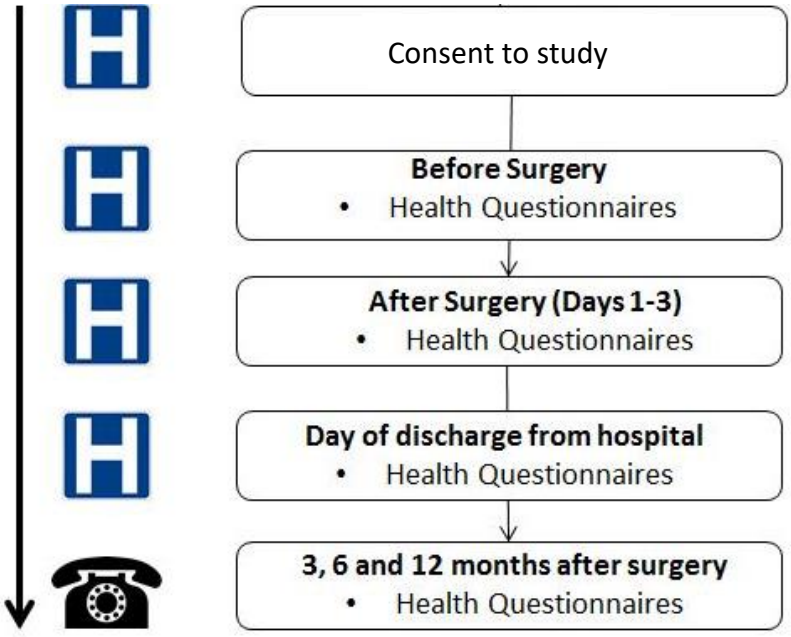
Both techniques are widely used and your anaesthetist is able to provide either technique.

What will I have to do if I agree to participate in the study?

The research team will follow your progress during your hospital stay and record any problems which you may experience after your operation. Data collection will be prior to your operation, immediately after your operation, the day you are discharged from hospital, and up to 12 months after you go home, as shown in the diagram (below). We will collect data on several occasions to establish how much pain you have experienced and how much pain relief you need.

The best way for us to record the pain you experience is by asking you. This will be done in the form of completing questionnaires. The questionnaires will ask about any pain you may have and how it has affected your day to day life. Each questionnaire should take no more than 30 minutes to complete.

With your permission, we will ask you to complete the questionnaires before your operation, during your hospital stay, on the day you are discharged and at 3, 6 and 12 months after you have gone home, as shown in the diagram below. While you are in hospital you can complete the forms there and when you are discharged from hospital you will have the option of either receiving paper questionnaires with pre-paid envelopes or being asked to respond to the research nurse over the phone. The questions you are asked will be the same whichever method you choose. The questionnaires have been carefully designed with the help of patient and public involvement to cause as little burden as possible whilst still collecting the information the study needs, but are in addition to your usual care.



Involvement of General Practitioner

With your permission we will contact your GP to inform them of your participation in the study so they are fully aware of your clinical treatment. We may also contact them to see if there have been any changes in your circumstances during the study.

What are the possible benefits of taking part?

This study will help us to find out which injection technique is better at reducing chronic (long-term) pain for patients undergoing thoracotomies. Whilst there may be no immediate benefits to you, the aim will be to improve the longer term pain relief and future care for patients who have open lung surgery.

What are the possible disadvantages and risks of taking part?

Taking part in this study will not present you with an increased level of risk.

Paravertebral block and thoracic epidural block are both widely used to provide pain relief to patients during and after major surgery. There are known side effects to both anaesthetic techniques, as shown below.

Discomfort on insertion (10%)
Inability to pass urine (10%)
Low blood pressure (10%)
Itchy skin (10%)
Inadequate pain relief (10%)
Nausea and Vomiting (1%)
Slow breathing (0.1%)
Temporary nerve damage (0.1%)
Catheter infection (catheter only used if temporarily unable to pass urine)
Permanent nerve damage (1 in 6,000 to 1 in 12,000)

Taking part in the study will not add to these side effects.
You will be closely monitored by the research team.

What happens when the research study stops?

The follow up period is 12 months in this study and this will be alongside, or in addition, to the follow-up you will receive from your consultant. After the study visits finish, you will be followed up as normal by your named

consultant at the hospital. After the completion of the research study, the results of the study will be available via the TOPIC 2 website.

Who is organising and funding the research?

The study is sponsored by the University of Birmingham (meaning The University of Birmingham has accepted certain legal and ethical responsibilities for the study), is being coordinated by the Birmingham Clinical Trials Unit (BCTU) and is funded by the government through the NIHR Health Technology Assessment (HTA) programme.

How have patients and the public been involved in this study?

Members of the Clinical Research Ambassador Group (CRAG) based at Heart of England NHS Foundation Trust, and other independent patient and public representatives helped to develop this research topic and the research questions that should be asked. The members of this group are lay people; however some are also co-applicants and will continue to be involved closely with the progress of the study.

In designing this study we have taken into account patient opinions on the frequency of participant visits and the tests that we will carry out.

However the conduct of the study is entirely in the hands of very experienced clinical staff and no lay person has any access to your personal health or care records or is able to influence your treatment.

Who has reviewed the study?

All research which takes part in the NHS is looked at by an independent group of people which protect the patient interests. This group is called a Research Ethics Committee (REC) and TOPIC 2 has been reviewed and given a favourable opinion by South East Scotland REC 01 Research Ethics Committee.

Will my taking part in this study be kept confidential?

All information collected about you for this study will be subject to the General Data Protection Regulation and Data Protection Act 2018 for health and care research and will be kept strictly confidential. University of Birmingham is the Sponsor for this study. The University of Birmingham will be using information from your medical records in order to undertake this trial and will act as the data controller for this study. This means that the University of Birmingham are responsible for looking after your information and using it properly. University of Birmingham

and the NHS will keep identifiable information about you for at least 25 years after the study has finished, to allow the results of the study to be verified if needed.

All information collected by the Sponsor will be securely stored at the Trials Office at the University of Birmingham on paper and electronically and will only be accessible by authorised personnel. The only people in the University of Birmingham who will have access to information that identifies you will be people who manage the study or audit the data collection process.

The NHS will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the trial. With your permission, your research doctor will notify your GP that you intend to participate in the study. They will also send a copy of your signed consent form in the post to the Trials Office.

In the Trials Office, you will be identified by a unique study number. In routine communication between your hospital and the Trials Office, you will only be identified by study number, initials and date of birth. Data may be provided to the Trials Office on paper or electronically.

By taking part in the study, you will be agreeing to allow research staff from the Trial Team at the University of Birmingham to look at the study records, including your medical records. It may be necessary to allow authorised personnel from government regulatory agencies, the Sponsor and/or NHS bodies to have access to your medical and research records. This is to ensure that the study is being conducted to the highest possible standards. Anonymised data from the study may also be provided to other third parties for research, safety monitoring or licensing purposes.

From time to time we may be asked to share the trial information (data) we have collected with researchers running other studies in this organisation and in other organisations so that they can perform analysis on the data to answer other important questions about chronic pain. These organisations may be universities, NHS organisations or companies involved in health research and may be in this country or abroad. Any such request is carefully considered by the study researchers and will only be granted if the necessary procedures and approvals are in place. This information will not identify you and will not

be combined with other information in a way that could identify you. The information will only be used for the purpose of health research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance. Under no circumstances will you be identified in any way in any report, presentation or publication arising from this or any other study.

All individuals who have access to your information have a duty of confidentiality to you.

You can withdraw your consent to our processing of your data at any time. Your rights to access change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. Under the provisions of the General Data Protection Regulation (GDPR) 2018, you have the right to know what information the Trials Office has recorded about you. If you wish to view this information, or find more about how we use this information, please contact Legal Services at the address below. Please note that a small fee may be payable to retrieve this information.

Legal Services

University of Birmingham

Edgbaston

Birmingham, B15 2TT

What if something goes wrong?

We do not envisage any problems occurring as a result of your participation in the study. However, all patients are covered for negligent harm according to NHS indemnity guidelines. If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions <*insert contact number*>. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you. Copies of these guidelines are available on request. If you wish to complain about how you have been treated during this study please contact Patient Advice and Liaison Service (PALS) at your local hospital.

Local hospital contact details here:
http://www.doh.gov.uk/patientadviceandliaisonservices/

What if I do not want to take part?

It's up to you to decide whether or not to take part. If you do decide you want to take part you will be given a copy of this information sheet to keep and will be asked to sign a consent form.

You may change your mind about taking part in any aspect of the study at any time (before the start of the study or even after you have commenced the study) for whatever reason without having to justify your decision and without any negative impact on the care you will receive from the medical staff. Exactly what happens if you change your mind (withdraw) depends on which parts of the study you have agreed to and when you withdraw.

If you agree to take part in the study and then wish to withdraw before the operation, you will be offered the usual treatment at your hospital. If you have agreed to take part but then decide not to continue with the study after your operation, your care will continue in the usual way.

Data collected up until withdrawal will be used, anonymously as part of the study outcomes.

What happens if new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, a member of the research team will tell you and discuss whether you should continue in the study. You will have the option to decide whether you wish to continue and a member of the research team may ask you to re-sign a consent form if you decide you to continue.

What will happen to the results of the research study?

The results and conclusions will be published in peer reviewed journals and presented at academic meetings. No individual will be identified in any publication.

Do you have any further questions?

For further information please contact:

TOPIC 2 Trial Office
Birmingham Clinical Trials Unit
University of Birmingham
Edgbaston
Birmingham B15 2TT
Telephone number: 0121 415 9134

Or your local investigator:*[insert contact details]*

If you would like to gain independent advice relating to trial participation you can contact Professor Tom Treasure, Emeritus Professor of Thoracic Surgery and Retired Thoracic Consultant Surgeon, University College London

Tel: 07957168754

Email: tom.treasure@gmail.com

Thank you for reading this information sheet