CONSENT FORM

TITLE: Management of occult pneumothoraces in mechanically ventilated patients - Calgary pilot study

SPONSOR: Canadian Intensive Care Foundation

INVESTIGATORS: Principal Investigator: Dr. Andrew Kirkpatrick
Co-Investigators: Dr. Rosaleen Chun
Dr. John Kortbeek
Dr. Rohan Lall
Dr. Kevin Laupland
Dr. David Zygun

This consent form is only part of the process of informed consent. It should give you the basic idea of what the research is about and what your participation will involve. If you would like more detail about something mentioned here, or information not included here, please ask. Take the time to read this carefully and to understand any accompanying information. You will receive a copy of this form.

BACKGROUND

You are being asked to participate in a medical research study being done by Dr. Andrew Kirkpatrick and the Trauma Services Team at Foothills Medical Centre. Before you decide whether or not to participate, it is important for you to understand why the research study is being done and what it involves.

You are being asked to participate because you have a lung condition called an occult pneumothorax (OPTX). An OPTX is a type of collapsed lung. This means that there is a collection of air around the lung that cannot be seen on a regular chest x-ray, but that is seen on CT scan (the special x-ray that you had). This lung condition is common in trauma patients. The concern that doctors have is that an OPTX can increase in size, especially if a patient needs a mechanical ventilator (a machine that helps you breathe). If an OPTX increases in size, it can become harder for your lung to inflate normally as you breathe. This can make it harder for your body to get oxygen, and in very rare cases, can result in death. On the other hand, an OPTX may not increase in size, and is simply absorbed by your body without causing harm. Traditionally, a pneumothorax is treated by inserting a hard plastic tube into the chest to drain the air out. This is done routinely under local anesthetic (or "freezing"). However, there are possible complications caused by chest tubes. Most patients report that chest tubes are painful. Less common complications include bleeding, infection, damage to the lungs and other organs in the chest, and pneumonia.

There is no good scientific evidence that a chest tube is necessary for a patient with a small or medium-sized OPTX. While some doctors prefer to use chest tubes all of the time, others believe that there is no good evidence that they prevent an OPTX from getting bigger and causing problems. Here at Foothills Medical Centre, we have reviewed the treatment of patients with occult pneumothoraces (OPTXs). We found that different doctors choose different treatments, and that their choices are not predictable. A particular doctor might use a chest tube on one day, but then not use a chest tube in a similar situation the next day. At the present time, we don't know which treatment is better. We are doing this study to learn the best way to help patients with OPTXs like yours.

The study is designed to find out if a chest tube is necessary for a trauma patient who has a small or medium-sized OPTX, and who also needs a ventilator (a breathing machine). Because of your injuries, you will be going to the operating room for surgery. While you are in the operating room (and perhaps for a while after as well), you will be connected to a breathing machine. In this study, the decision to insert a chest tube is made at random (by chance, like flipping a coin). If you choose to participate, there is a 50% chance that you will receive a chest tube and a 50% chance that you will just be monitored closely. If you are randomly chosen to have a chest tube inserted, this will be done in the operating room after your anesthetic is given (when you are "asleep"). If you are randomly chosen to be closely monitored, you may still have a chest tube inserted at any time if your doctor thinks your OPTX is getting bigger or is causing you problems.

We want to include 50 patients in this pilot study. Patients from hospitals in Calgary, Toronto and Quebec are participating. At the end of the pilot study, we will know if patients are willing to participate in this study and if our study procedures are acceptable to patients and their doctors. We will use the results of the pilot study to plan a larger study. The information from the pilot study will also be included in the larger study.

WHAT IS THE PURPOSE OF THE STUDY?

This study will help us learn if it is safe to treat patients with small or medium-sized occult pneumothoraces (OPTXs) by watching them closely and treating them as needed, or if it necessary to put a chest tube in as soon as the OPTX is diagnosed. Eventually, we will need to study several hundred patients to answer this question. This pilot study is the starting point for a larger study. As mentioned above, it will help us plan the larger study. It will also give us very important information about how well each treatment option works and how often patients in each study group have breathing problems.

WHAT WOULD I HAVE TO DO?

If you choose to join the study and are randomly chosen to be in the "observation only" group, you will receive your usual health care. Your doctors and other health care providers will monitor you very closely for any signs of breathing problems. You will not need any extra tests (like blood tests or x-rays) over and above those you would normally have. If, at any time, your doctor decides that a chest tube is needed to treat your OPTX, you will have one inserted immediately. This is part of the usual care for an OPTX that is causing problems, and you will receive all of the usual care and monitoring that goes along with having a chest tube.

If you are randomly chosen to be in the "chest tube" group, a small, hard plastic tube will be inserted between your ribs while you are in the operating room having surgery for your other injuries. Having a chest tube inserted is a simple procedure that usually takes a few minutes. It will be done after your anesthetic is given (when you are "asleep"), and it will not interfere with your other surgery. The chest tube will be connected to a small drainage system, and you may see air (bubbles in the container) or fluid draining out. Once the tube stops draining and/or your usual chest x-rays show that your OPTX has gone away, the tube will be taken out and you will be monitored closely for any breathing problems. A chest tube usually stays in for a few days, and you will receive pain medication as needed if you find it painful. You will be monitored closely by your doctors and other health care providers, and you will have the usual blood tests and x-rays that patients with chest tubes normally have. The number of tests needed will be determined by your doctor depending upon your condition. No tests or procedures beyond this usual care are required for the study.

Regardless of which study group you are in, you will be followed closely throughout your hospital stay. The research coordinator will review your medical chart for information about your medical situation, the types of injuries that you had, the type of treatment you needed, and whether or not you had any breathing difficulties.

WHAT ARE THE RISKS?

Having a chest tube inserted is usually a simple procedure that is common in trauma patients. There are possible complications, however. Most patients report that a chest tube is painful, but pain medication is given as needed. Less common complications that occur in up to 25% of patients include incorrect positioning of the tube (it isn't in the right place to drain the air), bleeding, infection, damage to the lungs or other organs in the chest, and pneumonia. Most complications are not life threatening, but in extremely rare cases, they can cause death. It is important for you to understand that even if you are selected for the "observation only" group, your doctor may decide at any time that you require a chest tube. If an OPTX gets bigger and causes a person breathing difficulty, putting in a chest tube is considered the usual treatment.

An OPTX that is not treated with a chest tube may increase in size, which can make it harder for your body to get oxygen. This can cause breathing difficulty, and in very rare and severe cases,

death. It is very unlikely that you would experience serious harm if you are in the "observation only" group, as your doctor would immediately insert a chest tube if he or she felt it was necessary. You will be under constant supervision by doctors and nurses in the operating room, and in the Intensive Care Unit if you are admitted there after your surgery. You will also be watched closely every day once you are transferred to a regular hospital unit.

ARE THERE ANY REPRODUCTIVE RISKS?

No.

WILL I BENEFIT IF I TAKE PART?

If you agree to participate in this study there may or may not be a direct medical benefit to you. However, the information we get from this study may help us choose the best treatment in the future for patients with small or medium-sized occult pneumothoraces (OPTXs).

DO I HAVE TO PARTICIPATE?

No, participation is completely voluntary. Whether or not you choose to join the study is up to you. Whatever choice you make, your decision will not have any effect on your current or future medical treatment or health care. If you would prefer not to participate, you do not have to explain why. You can also ask to be removed from the study at any time without giving a reason. If you choose to participate, but then change your mind, you should call Dr. Kirkpatrick or his research coordinator (Corina Tiruta) as soon as possible. Their telephone numbers are at the end of this form.

Dr. Kirkpatrick may also withdraw you from the study at any time if he feels it is in your best interests. For example, if early information from the study shows that patients who have chest tubes inserted clearly do much better (or worse) than patients who do not, the study would be stopped. You would then be treated in the best available way based on this information.

If the researchers learn any new information during the study that might affect your willingness to continue to participate, you will be informed as soon as possible. This may include new information from other studies, or new information about the risks and benefits of being part of the study.

WHAT ELSE DOES MY PARTICIPATION INVOLVE?

In addition to monitoring you throughout your hospital stay, we would like to check on you after you leave. With your permission, Dr. Kirkpatrick or the research coordinator will contact you by telephone 30-60 days after you are discharged to ask about any breathing problems you may have had.

WILL I BE PAID FOR PARTICIPATING, OR DO I HAVE TO PAY FOR ANYTHING?

You will not be paid for participating in this study. You do not have to pay for anything related to this study, as it only involves treatments that are regularly used for a patient with an OPTX.

WILL MY RECORDS BE KEPT PRIVATE?

All of your personal information (information about you and your health that identifies you as an individual), whether you choose to participate or not, will be kept private and confidential. All of the study records will be kept in a locked office that requires a security code for entrance. Only the study personnel and the University of Calgary Conjoint Health Research Ethics Board (CHREB) may access your records. The CHREB has approved this study, and will only have access to your personal information for purposes associated with the study. The CHREB will only be allowed to access your records under the supervision of Dr. Kirkpatrick. All personnel with access to your records will be obligated to protect your privacy. None of your personal information will be given to anyone without your permission unless required by law. When the results of this study are published, your identity will not be disclosed.

IF I SUFFER A RESEARCH-RELATED INJURY, WILL I BE COMPENSATED?

In the event that you suffer injury as a result of participating in this research, no compensation will be provided to you by the Canadian Intensive Care Foundation, the University of Calgary, the Calgary Health Region or the Researchers. You still have all your legal rights. Nothing said in this consent form alters your right to seek damages.

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding your participation in the research project and agree to participate as a subject. In no way does this waive your legal rights nor release the investigators, or involved institutions from their legal and professional responsibilities. You are free to withdraw from the study at any time without jeopardizing your health care. If you have further questions concerning matters related to this research, please contact:

Dr. Andrew Kirkpatrick (403) 944-2888

or

Corina Tiruta (research coordinator) (403) 944-1443

If you have any questions concerning your rights as a possible participant in this research, please contact the Ethics Resource Officer, Internal Awards, Research Services, University of Calgary, at 220-3782.

Participant's Name	Signature and Date/Time
Investigator/Delegate's Name	Signature and Date/Time
Witness' Name	Signature and Date/Time

The University of Calgary Conjoint Health Research Ethics Board has approved this research study.

A signed copy of this consent form has been given to you to keep for your records and reference.