SURROGATE 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 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 give consent for the person you represent 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 give consent, it is important for you to understand why the research study is being done and what it involves.

The person you represent has 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 the person 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 a person breathe). If an OPTX increases in size, it can become harder for the lung to inflate normally as a person breathes. This can make it harder for the 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 the 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.

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). In this study, the decision to insert a chest tube is made at random (by chance, like flipping a coin). If you consent, there is a 50% chance that the participant will receive a chest tube and a 50% chance that he/she will be monitored closely. If the participant is randomly chosen to be closely monitored, a chest tube may still be inserted at any time if the OPTX gets bigger or causes problems.

In addition to other injuries, the person you represent has an OPTX. Because he/she is on a breathing machine and is currently unable to make a decision about being in the study, we are asking you to provide a "surrogate consent". This means that we will enroll the person in the study with your permission as the legal guardian. When the person is no longer on a breathing machine and is awake and able to make decisions again, we will speak with him/her to explain the study and see if he/she wishes to remain in it.

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, the people who represent them, 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 THE SUBJECT HAVE TO DO?

A research subject who is randomly chosen to be in the "observation only" group will receive usual care. The subject's doctors and other health care providers will monitor him/her very closely for any signs of breathing problems. No extra tests (like blood tests or x-rays) over and above those that are part of usual care will be needed. If, at any time, the subject's doctor decides that a chest tube is needed to treat the OPTX, one will be inserted immediately. This is part of the usual care for an OPTX that is causing problems, and the subject will receive all of the usual care and monitoring that goes along with having a chest tube.

A research subject who is randomly chosen to be in the "chest tube" group will have a small, hard plastic tube inserted into the chest between the ribs to drain the air around the lung. Having a chest tube inserted is a simple procedure that usually takes a few minutes. It will be done under local anesthetic (or "freezing"). The chest tube will be connected to a small drainage system, and air (bubbles in the container) or fluid may drain out. Once the tube stops draining and/or the subject's usual chest x-rays show that the OPTX has gone away, the tube will be taken out and the subject will be monitored closely for any breathing problems. A chest tube usually stays in for a few days, and pain medication is given as needed. The subject will be monitored closely by his/her doctors and other health care providers, and will have the usual blood tests and x-rays that patients with chest tubes normally have. The number of tests that are needed will be determined by the subject's doctor, depending on his/her condition. No tests or procedures beyond this usual care are required for the study.

Regardless of which study group the subject is in, he/she will be followed closely throughout his/her hospital stay. The research coordinator will review the subject's chart for information about his/her medical situation and injuries, the type of treatment that was needed, and if the subject 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 the research subject is selected for the "observation only" group, his/her doctor may decide at any time that a chest tube is required. 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 the body to get oxygen. This can cause breathing difficulty, and in very rare and severe cases,

death. It is very unlikely that the research subject would experience serious harm if he/she is in the "observation only" group, as a chest tube would be inserted immediately if it became necessary. The subject will be under constant supervision by doctors and nurses while in the Intensive Care Unit, and will be watched closely every day once he/she is transferred to a regular hospital unit.

WILL THE SUBJECT BENEFIT IF THEY TAKE PART?

If you agree to allow the research subject to participate in this study, there may or may not be a direct medical benefit to him/her. 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).

DOES THE SUBJECT HAVE TO PARTICIPATE?

No, participation is completely voluntary. Whether or not you choose to give permission for the person you represent to join the study is up to you. Whatever choice you make, your decision will not have any effect on the person's current or future medical treatment or health care. If you choose not to have the person participate, you do not have to explain why. You can also ask that the person be removed from the study at any time without giving a reason. If you choose to give consent now, 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 the subject from the study at any time if he feels it is in his/her 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. The person 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 allow the subject 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 PARTICIPATION INVOLVE?

In addition to monitoring the research subject throughout his/her hospital stay, we would like to check on him/her after discharge. With your permission (or the subject's permission if he/she is able to consent), Dr. Kirkpatrick or the research coordinator will call 30-60 days after discharge to ask about any breathing problems the person may have had.

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

Neither you nor the research subject will be paid for participating in this study. Neither you nor the research subject will 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 THE RECORDS BE KEPT PRIVATE?

All of the subject's personal information (information about the subject or his/her health that identifies him/her as an individual) 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 the records. The CHREB has approved this study, and will only have access to the subject's personal information for purposes associated with the study. The CHREB will only be allowed to access the records under the supervision of Dr. Kirkpatrick. All personnel with access to the records will be obligated to protect the subject's privacy. None of the subject's personal information will be given to anyone without permission unless required by law. When the results of this study are published, the subject's identity will not be disclosed.

IF THE SUBJECT SUFFERS A RESEARCH-RELATED INJURY, WILL WE BE COMPENSATED?

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

SIGNATURES

Your signature on this form indicates that you have understood to your satisfaction the information regarding participation in the research project and agree to allow the person you represent to participate. 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 the subject from the study at any time without jeopardizing their 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 in this research, please contact the Ethics Resource Officer, Internal Awards, Research Services, University of Calgary, at 220-3782.

Participant's Name	
Surrogate'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.

REGAINED CAPACITY CONSENT FORM

Because your illness or injury made it impossible for you to participate fully in the informed consent process, the consent of your surrogate (legal guardian) was obtained on your behalf. Your surrogate believed you would have wished to participate in this research if you had been able to express your own opinion at the beginning of the research project.

As noted earlier, the process of informed consent must go on throughout a research project. This means that patients have the right to change their minds and, therefore, must be given opportunities to voice any changes they might wish. In your situation, you are now being given the opportunity to agree or disagree with the decision made by your surrogate for you to participate.

Please check the appropriate boxes to indicate your decision:

- ☐ I agree with my surrogate's decision.
- ☐ I do not agree with my surrogate's decision.

- ☐ I wish to remain in the study.
- ☐ I wish to withdraw from the study.

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

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

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