PATIENT INFORMATION SHEET

Ultrasound versus landmark identification of the cricothyroid membrane in emergency department patients undergoing computed tomography of the cervical spine: a randomised, single blind, clinical trial.

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You are invited to participate in the Ultrasound versus Landmark Identification of the Cricothyroid Membrane study which aims to determine which of these two techniques is the most accurate and rapid in identifying the cricothyroid membrane. This study is being conducted by Dr. Christopher Partyka (Emergency Medicine Staff Specialist, *X*), Dr Ian Ferguson (Emergency Medicine Staff Specialist, *X*), Dr Susan Stace (Emergency Medicine Staff Specialist, *X*), Dr Leon Lam (Radiology Staff Specialist, *X*) and Dr Minh Truong (Radiology Staff Specialist, *X*). This is a research project and participation is entirely voluntary. You can withdraw from the study at any time. Please read this information carefully, and feel free to ask any questions.

Once you understand what the project is about, and if you agree to participate in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you understand the information and that you give your consent for you to participate in this research.

Background and Aims of the study.

A small number of patients who are brought to the emergency department need a general anaesthetic. This lets us help them by keeping their airway open and breathing for them, and allows us to perform tests and provide further treatment.

To do this, we give anaesthetic medicines (sedatives and muscle relaxers) through a drip in the vein, to allow us to place a tube in the trachea (windpipe). We can then ventilate (push air in and out of) their lungs through this tube.

In very rare cases, after the medicines have been given, the breathing tube cannot be passed through the mouth. This is a life threatening emergency, and an emergency procedure called a cricothyroidotomy then has to be performed. This involves making a cut in the front of the neck, directly into the windpipe, so that the breathing tube can be put directly into the airway. This is similar to a tracheostomy.

The area of the neck where the cut is made is called the cricothyroid membrane, and it is usually identified by feeling the front of the neck with a finger. Recently, it has become clear that ultrasound scans can be used to locate the membrane, but it is not

clear if this is more or less accurate than locating it by feel, and whether using an ultrasound takes more or less time.

In this study, we aim to assess the accuracy and speed of cricothyroid membrane identification by feel, as compared to by using ultrasound.

Your Involvement and Procedures.

You have been asked to participate in this study because your treating doctor feels that you need a CT scan of neck to rule out a serious injury such as a fracture (broken bone) or dislocation.

You do not need an emergency general anaesthetic, and will not need a tube placed in your windpipe whilst you are in the emergency department.

The study aims to compare two groups of patients. One group will have their cricothyroid membrane identified by touch, and the other group will have it identified by ultrasound. If you agree to participate in the study, you will be randomly assigned (like tossing a coin) to one of these two groups.

Immediately before having your CT scan, a doctor will try and locate your cricothyroid membrane using either touch or ultrasound (depending on the group you were randomised to), and then place a marker (a small metal cross) on your neck, which will be held in place with adhesive tape.

After the CT scan, an x-ray specialist will then be able to see whether or not the marker has been placed accurately. We will then compare whether one method is more accurate than the other, as well as how long it took to place the marker.

Except for placing a marker on your neck, the rest of your care will be carried out as normal.

Participation in the study.

Participation in the study is completely voluntary. If you prefer not to participate, your CT scan will still be carried out, and your care will proceed as usual. If you agree to participate, but then decide to withdraw, you can do this at any time, and have the option of withdrawing all data collected so far.

Benefit to the Participant.

We cannot guarantee that you will receive any benefits from this project. However, your participation in the study will allow us to find out which of these cricothyroid localisation techniques is more accurate and/or faster than the other, which may benefit people with life threatening airway emergencies in the future.

Possible Risks to Participants.

Landmark identification of the cricothyroid membrane involves a doctor feeling the front of the neck with a gloved finger. Ultrasound identification involves putting gel on the front of the neck, followed by putting an ultrasound probe in the same place. Both of these techniques may involve moderate pressure over the front of the neck, but this should not be painful, and is not dangerous.

Data collection.

In order to evaluate the accuracy and efficiency of these two techniques, the research team will be collecting data about participating patients. Some of this is basic data about the person, such as age, height and weight as well as why the CT scan is being done. All of this will be collected routinely. For patients involved in the study, we will also be recording the accuracy with which the cricothyroid membrane was identified. This data will be collected from the radiology specialists reviewing the CT scan images.

Use of the data collected.

The information collected from this study will be stored in a de-identified fashion. This personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws, and the NSW Health Records and Information Privacy Act 2002. It is assured that all records dealing with participation in this study will be kept for seven years after completion of the study under secure conditions. Authorised persons within the institution may also inspect records for purposes of data audit only. Individual participants in the study will not be identifiable in any records of the data from the protocol or any publications resulting from the research.

Confidentiality.

All information gathered will remain confidential, and at no stage will information of a personal or confidential nature be divulged to researchers outside of the study group.

Feedback to the participants.

A summary of overall outcome of research will be informed to the participants of the study on expression of interest.

Ethical Guidelines and Approvals.

This project will be carried out according to the National Statement on Ethical Conduct of Research involving Humans (March 2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

The ethical aspects of this research project have been approved by the *X*.

The conduct of this study at Liverpool Hospital has been authorised by the South Western Sydney Local Health District, any person with concerns or complaints about the conduct of this study may also contact the Research Governance officer on (02) 8738 8304, email: research.support@sswahs.nsw.gov.auand quote project number HE16/337