LETTERHEAD

[DCD 10 -10 (Pilot Study): A spontaneous breathing test to assist prediction of time to death after cessation of cardio-respiratory support in organ donation]

INFORMATION FOR SENIOR NEXT OF KIN / PERSON RESPONSIBLE

Introduction

We thank you for your support of the organ donation process. We understand that participation in decision-making at the end of a loved one's life is not easy and that this is a very difficult time for you, your family and friends. Now, we would like to discuss with you an opportunity for your relative to participate in a research project that may help families such as your own in the future.

As you are now aware, the opportunity for a person to be an organ donor after circulatory determination of death (DCD) only arises if the doctors believe there is a high chance of death occuring within 90 minutes of ceasing cardio-respiratory support (that is, breathing assistance and heart support medications). If death does not occur quickly, there is a time where organs do not receive enough blood supply. This leads to organ damage and donation cannot proceed. We understand from past experience, that this period of uncertainty is hard for families and it can be very disappointing if organ donation does not occur.

The aim of our research is to find a way to better predict how long it will take for a person to die, and therefore improve ability to assess which patients are most suitable for organ donation. Trying to determine how long it will take for death to occur can be very challenging. Each patient has different illnesses, is on different medications and has different heart and lung function. Even though some research has been done in this area in the past, so far there is no easy way to predict how long it will take for death to occur after cessation of cardio-respiratory support.

What is the DCD 10-10 pilot trial?

The DCD 10-10 Pilot trial is a study currently being carried out at 7 major hospitals in Australia. It uses a simple breathing test, called the DCD 10-10 test, to look at how a patient is able to breath for themselves. We believe this test could help us improve our accuracy of prediction of death within 90 minutes of cessation of cardio-respiratory support from 70% to over 90%. This is a pilot study to see whether the breathing test is easy to perform and to ensure that is safe to use. If this study is successful in establishing the DCD 10-10 test, it is proposed that a larger study will be performed to look at its predictive value.

All patients for whom consent has been obtained for DCD are suitable for enrolment in this study. However, your relative will only be enrolled in the study with your written consent. We

encourage you to discuss this research invitation with other members of your family and to consider what your relative's wishes might be if they were able to communicate them at this time. If possible, this should be a joint decision of all those family members and friends who are close to, or care for your relative.

Where is the research being done?

The study is being conducted within this institution by

- PRINCIPLE INVESTIGATOR
  ASSOCIATE INVESTIGATOR

The study is part of a national collaborative study coordinated by researchers from the John Hunter Hospital, Newcastle Australia. It includes the following sites:

- The John Hunter Hospital, NSW
- The Royal North Shore Hospital, NSW
- The Royal Prince Alfred Hospital, NSW
- The Royal Brisbane and Women's Hospital, QLD
- The Tweed Hospital, QLD
- The Cairns Hospital, QLD
- The Royal Melbourne Hospital, VIC
- The Royal Adelaide Hospital, SA
- Flinder's Medical Centre, SA
- Lyell McEwan Hospital, SA

The study is being supported by a research grant from the John Hunter Charitable Trust Foundation.

Who can participate in the research?

This study is suitable for any patient over 18 years age, for whom consent has been obtained for organ donation via the 'DCD' pathway. Unfortunately, it is not suitable for those who are pregnant.

What choice do you have?

Consent for your relative's participation in this study is entirely voluntary. You should discuss the study and what it involves with all those who are close to, or care for your relative. You do not have to agree to your relative taking part in this research and your decision will be respected.

If you do decide to give consent for study participation, you can withdraw this consent at any time without having to give a reason.

Whatever your decision, please be assured that it will not affect your relative's ongoing management or your relationship with the staff who are caring for your relative.

What is involved in study participation?

If you agree to your relative's participation in this study, you will be asked to sign the Senior Next of Kin Consent Form.

Once the consent form is signed, the following activities and tests will take place:

- Medical information, including breathing rate, blood pressure and underling illness will be recorded.
- The treating ICU Specialist will be asked to make a prediction of when they think death will occur
- Within one hour of the planned withdrawal of cardio-respiratory support, the DCD 10-10 breathing test will be performed. This will involve transferring your relative from the ventilator onto a T piece device. This device supplies your relative with humidified room air to breath. All other treatment, including any pain relief and sedation will continue.
- The ICU doctor will observe breathing off the ventilator for up to 10 minutes. Breathing rate, oxygen levels, heart rate and blood pressure will be monitored and recorded. The breathing tube will be re-attached to the ventilator if there is a major change in breathing, or if the 10 minutes has elapsed.

You have the option of watching the DCD 10-10 test or waiting outside the room. You will be notified as soon as the test is finished so that you can spend time with your relative prior to the planned cessation of cardio-respiratory support prior to organ donation. The doctor can discuss the result of the DCD 10-10 test with you if you wish to know.

You will receive a letter once the DCD 10-10 pilot study is complete, summarising our findings.

What are the risks and benefits of participating?

Risks

All medical procedures, whether for diagnosis or treatment, routine or experimental, involve some risk. In addition, there may be risks associated with this study that are presently unknown and unforeseeable. This occurs in spite of all efforts to minimise these risks.

The main risks of this study are a change to patient blood pressure, heart rate, breathing rate or oxygen level during the test. We expect that if this does occur, these changes will be reversed once your relative is put back onto the ventilator. However, it is possible that changes to ventilator settings or additional drugs may be required to return these values to pre-test levels.

If your relative becomes unstable, the ICU Specialist doctor may decide that the risk of undertaking the DCD 10-10 test is too high. In this case all other study data, including the

doctor's prediction of time to death will be collected and used in the final analysis. This information will still be very helpful in studying doctor's predictions.

Benefits

This research provides an opportunity to contribute to furthering medical knowledge and to improve practices related to the process of organ donation. Since most Australians, when asked, are supportive of organ donation we hope that participation in this study might reflect the wishes of all of the patients involved in the study.

The DCD 10-10 test is not a treatment. It is important for you to know that this test will not benefit your relative directly, or change the course of their illness. Patients are only enrolled in this study when it is clear that they cannot survive without cardio-respiratory support. Some patients may be able to breathe quite well during the test because reflexes at the bottom of the brain are still active. However, this type of breathing does not allow someone to survive long term, nor does it mean that other areas of the brain are functioning normally. The DCD 10-10 test is only in the trial phase. At this time, the result of the test will not be able to tell us how long it will take for your relative to die once cardiorespiratory support is discontinued.

Will the study affect the organ donation process?

No. It is very important to us that all procedures around organ donation occur as usual.

There is a very small risk (perhaps < 1%) that your relative's heart may stop during the DCD 10-10 test. If this does occur, you and your family will be given a short time to spend with your loved one (2 – 5 minutes) and then organ donation will proceed immediately. This will ensure that your relative's wishes to be an organ donor are respected and enacted upon.

Will the study cost you anything?

Participation in this study will not cost you anything, nor will you or your relative be paid.

How will your privacy be protected?

All the information collected about your relative for the study will be treated confidentially, and only the researchers named above or the associate investigators at each site will have access. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in any such presentation.

Upon enrolment in the study, your relative will be assigned a re-identifiable study number. This ensures that all information collected is confidential. The researchers would, however, like to have access to your relative's medical record to obtain additional information relevant to this study once data collection has occurred. Only the Chief Investigator and Assistant Investigators at the lead site will have access to coding for patient re-identification.

The participant's personal information will be accessed, used and stored in accordance with Commonwealth Privacy Laws and the NSW Health Records and Information Privacy Act 2002.

If consent is withdrawn, data collection will cease immediately. You will be asked whether data collected up until the point of withdrawal can be used in the final data analysis. If the decision is to withdraw from the study completely, all the information collected from and about your relative will be removed from the study and all the data collected will be destroyed. Unfortunately, if final data analysis has already occurred, with your relative's data anonymously included in the study database, complete data erasure may not be possible.

As part of this study we will also be looking at how organ donation research affects families. We welcome any feedback about how we could improve the consent process or the information you receive. If you choose not to participate in the study, we will ask whether we can still document some basic information, such as patient medical record number, age and gender. This will help us determine the consent rate for the study, which may be useful when organising organ donation research in the future.

Further Information

When you have read this information, …… [name of researcher] will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact him/her on ……. This information statement is for you to keep.

Thank you for considering this invitation,

Dr Adelaide Charlton
Chief Investigator
Advanced Trainee in Intensive Care
John Hunter Hospital Newcastle, NSW

Complaints about this research

This research has been approved by the Hunter New England Human Research Ethics Committee of Hunter New England Local Health District, Reference 17/03/15/4.02
Should you have concerns about your rights as a participant in this research, or you have a complaint about the manner in which the research is conducted, you may contact the researcher directly. However, if an independent person is preferred, please contact Dr Nicole Gerrand, Manager, Research Ethics and Governance Unit, Hunter New England Human

Research Ethics Committee, Hunter New England Local Health District, Locked Bag 1, New Lambton NSW 2305, telephone (02) 49214950, email Hnehrec@hnehealth.nsw.gov.au

LETTERHEAD OF SENIOR RESEARCHER'S INSTITUTION

DCD 10 -10 (Pilot Study): A spontaneous breathing test to assist prediction of the time to death after cessation of cardio-respiratory support in organ donation

SENIOR NEXT OF KIN/ PERSON RESPONSIBLE CONSENT FORM

I, ...[Person Responsible name] of

……..... [address] on behalf of

…….[Patient name] of

…….[patient address]

have read and understand that the study will be conducted as described in the Information Statement, a copy of which I have retained.

I have been made aware of the procedures involved in the study, including any known or expected inconvenience, risk, discomfort or potential side effect and of their implications as far as they are currently known by the researchers.

I understand that patient participation in this study will allow the researchers and others to have access to the patient's medical record as described in the Information Statement and I agree to this.

I agree to participate in this study and understand that I can withdraw consent at any time without providing a reason.

I understand that my relative's personal information will remain confidential to the researchers.

I have had the opportunity to have questions answered to my satisfaction.

As Person Responsible, I hereby agree to patient participation in this research study.

NAME: _____

SIGNATURE: _____

DATE: _____

Declaration by person conducting the consent process

I, the undersigned, have fully explained this research to the person responsible named above.

NAME: _____

SIGNATURE: _____

DATE: _____