Participant Information Sheet

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| HREC No: | HREC/18/QPCH/183 |
| Project Title: | **Determining the Safety and Benefits of Exercising Tracheostomised Mechanically Ventilated Patients with Passy-Muir Speaking Valves** |
| Name of Researchers: | **Mr Luke Churchill, Dr Allison Mandrusiak, Mr Oystein Tronstad, Dr Jennifer Paratz, Dr Peter Thomas and Mr Lawrence Caruana** |

You are invited **to participate in a study determining whether using a speaking valve whilst exercising is safe and beneficial for patients receiving mechanical ventilation through a tracheostomy.**

Background

An admission to the Intensive Care Unit (ICU) may result in prolonged immobility, deconditioning, muscle weakness, reduced physical function and quality of life after hospital discharge. Depending on the type and severity of their condition, patients may require respiratory support in the form of mechanical ventilation (MV). A mechanical ventilator is a machine that helps patients breathe when they are not able to breathe well enough on their own.

During a period of prolonged MV or foreseeable prolonged ventilation, intensivists will consider whether patients would benefit from a tracheostomy. A tracheostomy (trache) is a surgically made hole in the front of the neck. This allows the doctors to place a tracheostomy (breathing) tube through the hole and into the trachea (windpipe). The other end of the tube is then connected to the ventilator.

When patients have a tracheostomy, a speaking valve can sometimes be added to the tube. Speaking valves are a one-way valve that allows patients to take a breath in via the tracheostomy tube. Breath out is redirected around the tracheostomy tube to the mouth and nose, enabling voice use. Speaking valves have proven to not only improve communication, but also to improve lung function for patients at rest. Whilst these are promising results for patients at rest, the effect on the lungs during physiotherapy or exercise is still unknown. We therefore don’t know whether the same benefits in lung functions apply when patients are exercising.

This study is important as it will assist physiotherapists in hospitals around Australia to determine whether it is safe and beneficial for patients with a tracheostomy to exercise with a speaking valve. If this is found to improve lung function during exercise, it will mean that patients will be able to participate more in exercise therapy whilst in the ICU. This may lead to better patient outcomes. It will also lead to more standardised practice across the country and potentially internationally.

This research will be conducted in the ICU at The Prince Charles Hospital. The associated researchers have all had experience in working with people admitted in ICU and have sufficient knowledge and capability to optimise the safeness of the current study. The study has been approved by the Human Research and Ethics Committees at The Prince Charles Hospital.

What will it involve?

All participants involved in this study will receive usual patient care, including surgical, medical, nursing, allied health and physiotherapy treatment.

If you agree to participate in the study, the exercise component will include five minutes of cycling either in bed or in a chair, starting with a resistance of zero and increasing the resistance by one level each minute. The MOTOmed® Letto is a lower limb cycle ergometer that allows the lower limbs to be trained passively, motor-assisted and actively. During exercise, your respiratory function will be monitored using two types of non-invasive equipment; Electrical Impedance Tomography (EIT) and Respiratory Inductance Plethysmography (RIP). These are monitors that use sensors placed on your skin. Data from these pieces of equipment will be collected.

We will also collect a range of information including details from your medical record such as age, sex, history of presenting conditions, medications taken, suburb of residence and occupation if available.

Benefits

It is unlikely that the study will lead to any benefits for you. We are hoping that the information gathered will lead to improvements for future patients.

There is currently no information available regarding whether it is safe to exercise tracheostomised patients with our speaking valves. There are indications that these valves can improve lung function when patients are at rest. By establishing whether it is safe to exercise tracheostomised patients with speaking valves; this may improve outcomes for future patients admitted to ICU such as:

* Decreased ICU and hospital length of stay
* Decreased time requiring mechanical ventilation
* Decreased health care costs
* Improved function on discharge from ICU
* Improved ability to communicate whilst exercising
* Decreased anxiety levels during exercises
* Improved long term physical function and quality of life

Risks and Side Effects

Exercise therapy is standard practice in the ICU. The only thing that is different to normal care is that one of the exercise sessions will be completed with a speaking valve. You will only receive lower limb training if deemed safe by the medical team and would receive exercise training as part of standard clinical practice. We will perform some non-invasive measurements during the exercise sessions. These carry no risk, and do not cause any discomfort.

Speaking valves have been shown to be beneficial for patients at rest. There is no evidence to suggest that it is detrimental to use a speaking valve whilst exercising.

Confidentiality and Privacy

All information that the research team collects about you is confidential. The information is stored in a secure location, and only the researchers will have access to the study information. Information will be kept in a secure location indefinitely, so that we can reliably answer questions that other researchers might ask about our findings.

When we have completed collecting information about you, we will remove identifying information (your name, address, etc.) from the database. Any publication or conference presentation or other public documents relating to the study will only contain grouped information, and no individual patient will be able to be identified.

Withdrawal from the study

You are able to withdraw from the study at any time, and you will continue to receive standard care from everyone involved in your care. The researchers recognize that some people might become too unwell to continue with the study. It is still useful for us to continue to collect information even if you are not able to participate completely, and if you do choose to withdraw, our research staff will ask if we can still obtain information from the Prince Charles Hospital health based information system after 12 months.

Further Information

Please discuss any questions you might have with the research staff when they come to ask your consent. For further information at any time through the study, you can contact the Principal Researcher who will help you directly.

Principal researcher:

Mr. Luke Churchill, The Prince Charles Hospital.

Phone: 07 3139 5310

Email: luke.churchill@health.qld.gov.au

Independent Contact

This study has been reviewed and approved by the Prince Charles Hospital Health Service District Human Research Ethics Committee. If at any time you have concerns about the study, wish to make an independent complaint, or wish to discuss your involvement with someone not connected with the study, you may contact the Research Governance Officer, The Prince Charles Hospital on 07 3139 4407 or email RGOTPCH@health.qld.gov.au who will forward concerns to the Chair, Human Research Ethics Committee.

Participant Consent Form

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I agree to participate in the above named project and in so doing acknowledge that:

1. I have been informed as to the nature and extent of any risk to my health or well-being.
2. I am aware that, although the project is directed to the expansion of medical knowledge generally, it may not result in any direct benefit to me.
3. I have been informed that my refusal to consent to participate in the study will not affect in any way the quality of treatment provided to me.
4. I have been informed that I may withdraw from the project at my request at any time and that this decision will not affect in any way the quality of treatment.
5. I have been advised that the Executive Director, The Prince Charles Hospital, on recommendation from The Prince Charles Hospital Metro North Human Research Ethics Committee has given approval for this project to proceed.
6. I am aware that I may request further information about the project as it proceeds.
7. I am aware that my GP may be informed that I am taking part in the project.
8. I understand that, in respect of any information (which may consist of records outside of this hospital); confidentiality will be maintained to the same extent as for my Hospital medical records. In the event of any results of the project being published, I will not be identified in any way.
9. I agree that, if necessary, my medical records (in respect of my involvement in this project) may be inspected by a Research Assessor. This assessor may be external to but approved by the Hospital, provided that the Assessor does not identify me or my hospital's medical records in any way to a third party.

Patient’s name: ....................................... Signature: .............................. Date:\_ \_ / \_ \_ \_ / \_ \_ \_ \_

 DD / MMM / YYYY

Name of Investigator: ................................Signature: ................................. Date:\_ \_ / \_ \_ \_ / \_ \_ \_ \_

 DD / MMM / YYYY

Revocation of Consent Form - Participant

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| --- | --- |
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1. I hereby wish to WITHDRAW my consent to participate in the research project described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with The Prince Charles Hospital Metro North Health Service District

Participant’s name (please print): .........................................................................................

(Signature).............................................................. Date:\_ \_ / \_ \_ \_ / \_ \_ \_ \_

 DD / MMM / YYYY

This Revocation of Consent should be forwarded to:

Luke Churchill

Physiotherapy Department

The Prince Charles Hospital

Rode Road

Chermside, 4032, Qld