MELBOURNE HEALTH

Passion for Caring - Achieving the Extraordinary

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Royal Melbourne Hospital

Title	The use of Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE) for pre-oxygenation in neurosurgical patients: a randomised controlled trial
Short Title	THRIVE
Protocol Number	*Version 2, Dated 10th January 2017*
Coordinating Principal Investigator/ Principal Investigator	Dr Irene Ng
Associate Investigator(s)	Dr Irene Ng, Dr Roni Krieser, Dr Paul Mezzavia Dr Keat Lee, Chun-Yiu Tseng, A/Prof Reny Segal, Ms Rochelle Cotter, Ms Sandy Hannon
Location	Royal Melbourne Hospital

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in this research project. This is because you are having a neurosurgical procedure. The research project is testing a new treatment for delivering oxygen before you are given general anaesthesia. The new treatment is called High Flow nasal oxygen.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to take part in the research project
• Consent to have the tests and treatments that are described
• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

2 What is the purpose of this research?

High Flow Nasal Oxygen is approved in Australia to treat low oxygen levels. It is commonly used in intensive care and emergency department. Recently, it has been increasingly used in anaesthesia. However, there are limited studies on its use in the anaesthetic setting. Therefore, we would like to know whether the oxygen level is higher when high flow nasal oxygen is used in pre-oxygenation compared to standard facemask technique.

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). You will have a 1 in 2 chance of receiving the high flow nasal oxygen.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions.

There are no additional costs associated with participating in this research project, nor will you be paid. All medication, tests and medical care required as part of the research project will be provided to you free of charge.

4 What do I have to do?

You are not required to do anything extra for this study. There are no restrictions on your lifestyle, diet, medications or ability to donate blood that occur because of your participation. As usual, after an anaesthetic you should not drive, operate heavy machinery or make significant financial or legal decisions, but you will receive an anaesthetic for your procedure regardless of whether you participate in the study.

5 Other relevant information about the research project

This is a study that is solely conducted at the Royal Melbourne Hospital, and is independent of any other studies. All of the researchers involved are employed by the Royal Melbourne Hospital.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Royal Melbourne Hospital.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. Other options are available to deliver oxygen to you before you are given anaesthesia; these include the standard facemask technique. Your study doctor will discuss these options with you before you decide whether or not to take part in this research project. You can also discuss the options with your local doctor.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, the results of this study may provide us with a better understanding of the high flow oxygen delivery device.

9 What are the possible risks and disadvantages of taking part?

Your anaesthetist will explain the risks of anaesthesia for the operation to you. For the pre-oxygenation phase of the anaesthesia, it will be performed as part of your normal care, there are no anticipated extra risks that you will be exposed to as a participant in this study. However, after you are given anaesthetic drugs, there are potential risks of low oxygen level and high carbon dioxide level during what we called the apnoea phase, i.e. when patients stop breathing. However, a few previous studies have shown that when patients received the high flow oxygen delivery device, their oxygen level remained at a safe level for a period of time and the carbon dioxide level rose at a very slow rate. The apnoea phase will be relatively short, about 60 seconds in our study. Therefore, we believe the risks of low oxygen level and high carbon dioxide level should be relatively minimal. Below is a table listing the potential side effects of using the high flow oxygen delivery device.

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Nasal discomfort	Occasionally	Minor	Until end of pre-oxygenation
Bleeding from the nose	Very rare	Minor to moderate	A short time during or after its use
Low oxygen levels	Rare	Minor to moderate	Until end of anaesthetic induction
High Carbon dioxide levels	Rare	Minor to moderate	Until end of anaesthetic induction

10 What will happen to my test samples?

Blood samples will be discarded after being analysed for the purpose of this research project.

11 What if new information arises during this research project?

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

12 Can I have other treatments during this research project?

There are no limitations on receiving other treatments during this research project.

13 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team that you wish to withdraw. There are no health implications for withdrawing from this research project.

14 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:
- Unacceptable side effects
- The device being shown not to be effective
- The device being shown to work and not need further testing

15 What happens when the research project ends?

No specific follow-up is required with participation in this study. If you choose to participate you will receive routine post-operative care and follow-up identical to if you had not been involved. However should you wish to contact someone at the end of this project, the principal researcher Dr. Irene Ng can be contacted on 03 93427540.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Each patient will be assigned a study number. The data will be labelled with the study number and not the patients' names. The data will be kept in a locked cabinet in the Department of Anaesthesia until all the participants have been recruited and will then be destroyed after 15 years. Only members of the research team will have access to the information. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Your health records and any information obtained during the research project are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the, the institution relevant to this Participant Information Sheet, The Royal Melbourne Hospital, or as required by law. By signing the Consent Form, you authorise release of, or access to, this confidential information to the relevant study personnel and regulatory authorities as noted above.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this research project may be recorded in your health records.
In accordance with relevant Australian privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.
Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

17 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

18 Who is organising and funding the research?

This research is being organised by anaesthetic staff at the Royal Melbourne Hospital who are receiving no funding for this research.

19 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Melbourne Health.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

20 Further information and who to contact

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on on 03 93427540, or the research nurses on 03 9342 8126 or any of the following people:

Clinical contact person

Name	Dr Irene Ng
Position	Staff Consultant Anaesthetist
Telephone	93427540
Email	Irene.Ng@mh.org.au

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

Reviewing HREC approving this research and HREC Executive Officer details

The Melbourne Health Human Research Ethics Committee (HREC) has approved this study. If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

Reviewing HREC name	Melbourne Health HREC
HREC Executive Officer	Manager HREC
Telephone	(03)9342 8530
Email	Research@mh.org.au

For MH site PICFs complaints contact person at MH:

Complaints contact person

If you have any complaints about any aspect of the project then you may contact:

Name	Director Research Governance and Ethics
Position	Complaints Manager
Telephone	(03)9342 8530
Email	Research@mh.org.au

Consent Form - *Adult providing own consent*

Title	The use of Transnasal Humidified Rapid-Insufflation Ventilatory Exchange (THRIVE) for pre-oxygenation in neurosurgical patients: a
Short Title	THRIVE
Protocol Number	Version 1, Dated 16/08/16
Coordinating Principal Investigator/ Principal Investigator	Dr Irene Ng
Associate Investigator(s)	Dr Irene Ng, Dr Roni Krieser, Dr Paul Mezzavia Dr Keat Lee, Chun-Yiu Tseng, A/Prof Reny Segal, Ms Rochelle Cotter, Ms Sandy Hannon
Location	Royal Melbourne Hospital

Declaration by Participant

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to the Royal Melbourne Hospital concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the study without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

Name of Participant (please print) _____

Signature _____ Date _____

Under certain circumstances (see Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 at 4.8.9*) a witness* to informed consent is required.*

Name of Witness* to Participant's Signature (please print) _____

Signature _____ Date _____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor/ Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Form for Withdrawal of Participation - *Adult providing own consent*

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Location	Royal Melbourne Hospital

Declaration by Participant

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with The Royal Melbourne Hospital.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.

Declaration by Study Doctor/Senior Researcher†

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

Name of Study Doctor/
Senior Researcher† (please print) _____

Signature _____ Date _____

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.