Place Participant Label Here

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Austin Health

Title	High-flow mouthguard versus conventional oxygen therapy for short, low-sedation-risk endoscopic procedures: a randomised single-blinded trial
Short Title	HFMG vs COT for low-risk short endoscopic procedures
Protocol Number	ND 63130/2020
Coordinating Principal Investigator/ Principal Investigator	Kim Hay Be
Associate Investigator(s)	Leonardo Zorron Cheng Tao Pu/Sujievvan Chandran/Philip Peyton/Rhys Vaughan/Marios Efthymiou/Brett Pearce/Matthew Lee/Luke Fletcher/Zee Lim/Rebecca Cogan
Location	Austin Health

Part 1 What does my participation involve?

1 Introduction

You are being invited to take part in this research project because you are about to have an endoscopic procedure to investigate or treat a medical condition. The research project is testing which of two oxygen devices with different oxygen flows work better during short endoscopic procedures: a standard nasal cannula at 2L/min or a high-flow mouthguard at 20L/min.

Endoscopic procedures might vary slightly depending on what is the target organ. For instance, an endoscopic procedure is called a gastroscopy when used to examine the lining of the stomach. Another example is when we investigate the bile duct and pancreas which can be done with two procedures depending on the area that needs investigation. These endoscopic procedures are called endoscopic ultrasound (or EUS) and side viewing endoscopy (or ERCP). Regardless of their specific names, all endoscopic procedures can be used for diagnostic and therapeutic purposes. For this study, all patients with low risk for sedation-related complications that will be submitted to short endoscopic procedures (expected to last less or equal to 20 minutes) are being invited to participate. Patients with low risk for sedation are defined through objective technical aspects such as obstructive sleep apnoea and body mass index.

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?

Doctors currently examine the human gastrointestinal tract using a device called an endoscope, which contains a camera that enables the doctor to view and treat diseases from within the gastrointestinal tract. Most endoscopic procedures are done under sedation, which means that people are put asleep during such procedures by an Anaesthetist. During the examination, it is costumery that the patients' breathing capabilities becomes mildly impaired. For this reason, the Anaesthetists utilise supplementary oxygen to avoid the oxygen levels in your blood getting too low. Although we know that using some supplementary oxygen is better than using none, it is still under debate what is the ideal amount (or flow) of oxygen that should be used to avoid the loss of oxygenation. The purpose of this study is to determine whether two devices that deliver two different flows of oxygen (standard nasal cannula - 2 L/min or high-flow mouthguard - 20L/min) are similar or different in preventing the loss of oxygenation while under sedation for short endoscopic procedures.

This research has been initiated by the study doctors, Professor Philip Peyton, Dr Sujievvan Chandran, Dr Kim Hay Be and Dr Leonardo Zorron Cheng Tao Pu.

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 be participating in a special type of randomised study called blind study. In a blind study you do not know which of the treatments you are receiving. However, your study doctor will know which treatment you are receiving.

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?

In addition to coming for your scheduled endoscopic procedure and filling out a short 'symptoms visual questionnaire' after the procedure is done, no other actions will be asked from you. You will not be required to undertake any restrictions or refrain to take any usual medications because of the study. However, as per standard of care, you may have restrictions to the use of some medications (e.g. blood thinners) and lifestyle/diet depending on the type of endoscopic procedure you will have. This will be advised by the endoscopy nurse prior to your procedure.

Restrictions after the procedure will be advised as per standard of care post-endoscopic procedures and are not related to this study. When fully recovered from the sedation, you will be instructed when to resume your usual diet (usually within a few hours) and your driver will be allowed to take you home. Because of the use of sedation, we mandate that you be taken home by a driver and not to drive or handle machinery for the remainder of the day. You should refrain from performing your daily duties until you are fully recovered from the effects of sedation. Daily medications can be taken as required.

Participation in this study will not result in a longer hospital stay beyond that required for a normal endoscopy. Your involvement in this study will cease once you are discharged from the hospital from the endoscopy encounter and you will not be required to attend the hospital

after this for research purposes. The time you spend in the hospital from admission/consent to discharge will largely depend on the endoscopic procedure you will be undertaking and the number and order of endoscopic procedures in your allocated endoscopy suite on the day. It can vary widely, but you should expect to spend in the hospital between 3 and 6 hours.

Before the procedure you will be asked if you want to be part of the study or not. This as all other research studies are voluntary and you are free to choose whether you want to participate or not. If, after clarifying your doubts about the study, you agree to participate, you will be asked to sign a consent form. Then, you will be directed to the endoscopy suite and sedated as per the standard of care. During your endoscopy and while still sedated, the supplemental oxygen device (either through nasal prongs/standard nasal cannula or the high-flow mouthguard) will be used. The flow set up by the anaesthetist will be either 2 L/min (for nasal prongs/standard nasal cannula) or 20L/min (for high-flow mouthguard), depending on a previously randomised order. After the procedure and before being discharged you will be asked to fill in a short questionnaire ('symptoms visual questionnaire') about pain and other symptoms such as dry mouth. If any of these are intense enough to warrant a medical evaluation, as per standard of care, you will remain in the unit until your symptoms settle and will be asked again how the symptoms are after about 30 minutes.

Although it is part of the standard of care asking the patient about his/her symptoms after the endoscopic procedure, this is usually only done verbally. The questionnaire we will use in this study is the only data that will be collected which is not part of the standard clinical care. All other information that will be collected for the study are already part of the standard of care.

5 Other relevant information about the research project

This is a single centre study to be conducted at Austin Health, Victoria. A total of 300 participants are expected to participate in this study. In this study one group will receive oxygen from the standard nasal cannula and the other one will get it from the high-flow mouthguard. All participants, regardless of which group they are on, will be using both the mouthguard (to protect the teeth and its contact with the endoscope) and the standard nasal cannula (that can be used either to administer oxygen or to measure carbon dioxide).

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 Austin Health.

7 What are the alternatives to participation?

You do not have to take part in this research project to receive treatment at this hospital. If you decide not to participate in the trial, the decision on what device and flow will be used will depend solely on the anaesthetist expertise and can consist in using either the standard nasal cannula at 2 or the high-flow mouthguard at 20 L/min. The endoscopic procedure will be carried out in the same way regardless if you participate or not in the research.

8 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this research. This study is being performed for research purposes and will not affect your medical treatment and/or diagnosis. You will not receive any direct benefit from participating in the study on this occasion. However, it is hoped that the results of the study will assist in defining an optimal approach to oxygen therapy during sedation of short endoscopic procedures.

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

Risk of bleeding and perforation are associated with endoscopic procedures regardless of the study. No additional biopsies or samples will be collected for the research. Although low, there is a small chance of headaches or dry mouth/nose after the use of high-flow mouthguard therapy.

In addition, there may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that you get.

These days, whilst anaesthesia is generally very safe there are some risks associated with anaesthesia. The most common problems associated with anaesthesia are feeling unwell or vomiting, bruising at the site of injections, sore throat or hoarse voice. Most patients do not have these problems. If these problems do happen, they usually get better very quickly. Damage to teeth may occur, but this is rare. The risk of brain damage or death due to anaesthesia is very rare.

The risk of problems from anaesthesia increases for patients who are having more major surgery, those with medical problems and those that require difficult anaesthetic procedures. If you have any concerns about these issues, you should discuss them with the study team.

10 What will happen to my test samples?

There will be no collection of test samples for study purposes.

11 What if new information arises during this research project?

You will be part of this research only during and shortly after your endoscopic procedure takes place. If during the procedure the anaesthetist understands that you require a different oxygen therapy regime than you have been randomised to, he/she is free to change it as he/she will. Even though you don't receive a selected flow throughout the whole procedure, your data will still be used for the study unless you actively ask us to withdraw you from the study. All data related to this research will be retained for 15 years according to the Australia Code of Conduct as this is a clinical trial.

If during the research period new information about the matter in study comes to light, the research team might decide to discontinue it. If this occurs, any prospective participants will be told about this new information and may mean that you can no longer participate in this research. If this occurs, the persons supervising the research may not invite you to participate. In all cases, you will be offered all available care to suit your needs and medical condition.

12 Can I have other treatments during this research project?

Although there are some limitations on medications due to your endoscopic procedure (e.g. blood thinners), there are no restrictions regarding 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.

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?

Non-identifiable research data will be used for scientific presentation and/or publication in scientific meetings/journals.

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. No information collected in this study will be used to identify you apart from the objectives of the study. Test results and information about your medical history will be used for the purpose of analysing the data for research purposes only. Research data will be kept by the clinical study investigators (identifiable data – physicians and nurses and re-identifiable data – other staff e.g. statistician) and used only for scientific presentation or publication if suitable (non-identifiable data).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.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

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 (non-identifiable information and group analyses).

In accordance with relevant Australian and Victorian 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 project is being conducted by Prof Philip Peyton, Dr Sujievvan Chandran and Dr Leonardo Zorron Cheng Tao Pu

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 Austin 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 doctors on 03 9496 5353 or any of the following people:

Clinical contact person

Name	[redacted]
Position	[redacted]
Telephone	[redacted]
Email	[redacted]

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:

Complaints contact person

Position	[redacted]
Telephone	[redacted]
Email	[redacted]

Local HREC Office contact

Position	[redacted]
Telephone	[redacted]
Email	[redacted]

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Consent Form - *Adult providing own consent*

Title	High-flow mouthguard versus conventional oxygen therapy for short, low-sedation-risk endoscopic procedures: a randomised single-blinded trial
Short Title	HFMG vs COT for low-risk short endoscopic procedures
Protocol Number	63130
Coordinating Principal Investigator/Principal Investigator	[redacted]
Associate Investigator(s)	Leonardo Zorron Cheng Tao Pu/Sujievvan Chandran/Philip Peyton/Rhys Vaughan/Marios Efthymiou/Brett Pearce/Matthew Lee/Luke Fletcher/Zee Lim/Rebecca Cogan
Location	Austin Health

Consent Agreement

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 Austin Health 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.

Austin HEALTH

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Declaration by Participant – for participants who have read the information

Name of Participant (please print) _____

Signature _____ Date _____

Declaration - for participants unable to read the information and consent form

Witness to the informed consent process

Name (please print) _____

Signature _____ Date _____

* Witness is not to be the Investigator, a member of the study team or their delegate. 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.

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

Place Participant Label Here

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

Title	High-flow mouthguard versus conventional oxygen therapy for short, low sedation risk endoscopic procedures: a randomised single-blinded trial
Short Title	HFMG vs COT for low-risk short endoscopic procedures
Protocol Number	63130
Coordinating Principal Investigator/Principal Investigator	Kim Hay Be
Associate Investigator(s)	Leonardo Zorron Cheng Tao Pu/Sujievvan Chandran/Philip Peyton/Rhys Vaughan/Marios Efthymiou/Brett Pearce/Matthew Lee/Luke Fletcher/Zee Lim/Rebecca Cogan
Location	Austin Health

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 Austin Health.

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.

Place Participant Label Here

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.