

**Participant Information Sheet/Consent Form**

**Interventional Study –** Adult providing own consent

**Monash Medical Centre, Clayton**

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| **Title** | Apnoeic Oxygenation: A comparison of Nasal Prongs to Nasopharyngeal Cannula on Oxygenation Before Intubation |
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| **Protocol Number** | 1 |
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| **Coordinating Principal Investigator/ Principal Investigator** | Dr. Emma Ford |
| **Associate Investigator(s)** | Dr. Michael Lukins |
| **Location**  | Monash Medical Centre, Clayton and Moorabbin Hospital, Moorabbin |

**Part 1: What does my participation involve?**

**1 Introduction**

You are invited to take part in this research project. This is because you require a general anaesthetic for surgery. The research project is comparing different devices for giving oxygen during the start of your anaesthetic. The different devices are called nasal prongs and nasopharyngeal cannula.

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?***.*

Medications, drugs and devices have to be approved for use by the Australian Federal Government. Nasal prongs and nasopharyngeal cannula are already approved in Australia to supply Oxygen to patients in hospital.

This research has been initiated by the study doctors, Dr Michael Lukins and Dr Emma Ford.

**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).

 All participants will receive Oxygen through a face mask before they are put to sleep for an operation. In addition, participants may receive additional Oxygen through nasal prongs or nasopharyngeal cannula. You will then be given anaesthetic medication and will go to sleep as normal. In this study, we would like to see how patients’ Oxygen levels in their throat change once they are asleep, enabling us to compare the different devices.

 You will either receive Oxygen delivered by **nasal prongs, pharyngeal cannula or neither**. You have a 40% chance of receiving nasal prongs, 40% chance of receiving nasopharyngeal cannula and 20% chance of having no device applied.

You are very welcome to look at these devices before you decide to participate, just ask your anaesthetist to show you. Nasal prongs are small tubes which go up into each nostril by about 1 cm. A nasopharyngeal cannula is a thin, flexible tube which is inserted through the nostril to sit at the back of the throat. Both of these will have Oxygen running through them. Once you are asleep and not breathing, we will measure and record the concentration of Oxygen you are receiving by each of these methods by inserting a small tube into your mouth. This is does not hurt in any way. After three minutes, or earlier if required, we will insert a breathing tube and continue the rest of the procedure as normal.

**Your safety and well-being is our priority**. These interventions are very unlikely to cause harm or disadvantage to you. However, we will always put your safety first and remove any of the devices and stop the study if it is interfering with delivering you our very best care.

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You will be participating in **a blind study**. In a blind study you do not know which of the treatments you are receiving. 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?**

You do not need to do anything differently to normal to participate in this study.

**5 Other relevant information about the research project**

 55 patients will be involved in this study between Monash Medical Centre and Moorabbin Hospital. 40 per cent of participants will have nasal prongs applied, 40 per cent nasopharyngeal cannula applied and 20 per cent (the control group) will have neither of these.

 It is hoped this study will add valuable information to how we can deliver Oxygen to participants having an anaesthetic and which devices are best to use for this. There has been lots of previous research addressing the same topic, but this study is the first to compare these two methods directly, and take samples of Oxygen levels from the mouth.

**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 Southern Health.

**7 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include increased Oxygen levels being delivered to you before the operation begins.

**8 What are the possible risks and disadvantages of taking part?***.*

Medical treatments often cause side effects. You may have none, some or all of the effects listed below. If you have any of these side effects after the surgery, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects when you are in recovery, after the operation is finished.

Application of nasal prongs or pharyngeal cannula

* May cause minor discomfort or irritation around the nostrils.
* May cause some increased nasal dryness from the Oxygen being delivered.
* May cause minor soft tissue damage around the nasal area.

These possible side effects are rare, temporary and usually relieved once the device is removed. You will be asleep soon after these devices are applied so any discomfort will be minimal.

 There is also a small risk that your Oxygen levels may fall during the period of time you are not breathing. These levels are always monitored very closely by your anaesthetist. However, if your Oxygen levels start to fall at any point during the procedure, we will start breathing for you.

**9 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 devices being used are not in the best interests of the participants.

**10 What happens when the research project ends?**

We hope to analyse the results of this research and enable anaesthetists and other practitioners to consider more effective means of supplying their patients with Oxygen. It is hoped that this study will prompt further research into the area and larger trials being conducted in the future. Depending on our conclusions from this study, the results may be published, or referred to in medical literature, conferences or posters.

**Part 2: How is the research project being conducted?**

**11 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. Information will be collected with you Southern Health UR number (a code) on it. This allows the researchers to confirm any medical details though the Southern Health medical records system, if we need to.

Your weight, height, age and sex **will** also be recorded so we can analyse the results accurately. Your name and any other personal details will **not** be recorded on the study collection forms. Recorded 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.

Our study forms will remain confidential and will be securely stored in the Department of Anaesthetics a Monash Medical Centre. It will **not** be uploaded onto your medical records. Only the two researchers named at the top of this document will have access to your data.

We intend to retain all information collected from the study forms for as long as we need to analyse the results and transfer the data to a computer, which requires a personal security password to access.

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. Research findings will not include any identifiable, re-identifiable or personal information. General characteristics of patients will be described, such a weight, height, Oxygen levels, sex and age for the purpose of comparing treatment groups.

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. 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.

**12 Complaints**

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.

**13 Who is organising and funding the research?**

This research project is being conducted by Dr Emma Ford and Dr Mike Lukins, from the Department of Anaesthetics, Monash Medical Centre. No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

**14 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 Monash Medical Centre.

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.

**15 Further information and who to contact**.

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 03 9594 6666 (via Switchboard at Monash Health, and ask for Dr Emma Ford or Dr Mike Lukins)

 **Clinical contact person**

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| --- | --- |
| Name | Dr Emma Ford |
| Position | Anaesthetics Registrar |
| Telephone | 0419 596 304 |
| Email | emmaford77@gmail.com |

**Complaints contact person**

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 | *[Name of HREC]* |
| HREC Executive Officer | *[Name]* |
| Telephone | *[ HREC Executive Officer Phone number]* |
| Email | *[ HREC Executive Officer Email address]* |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Local HREC Office contact (Single Site - Research Governance Officer)**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

**Consent Form -** *Adult providing own consent*

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| **Title** | Apnoeic Oxygenation: A comparison of Nasal Prongs to Nasopharyngeal Cannula on Oxygenation Before Intubation |
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**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 Southern 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.

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|  |
|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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|  |
|  | Name of Witness\* to Participant’s Signature (please print) |  |  |
|  |
|  | Signature |  |  Date |  |  |
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\* 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.

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|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† 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.