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theAlfred

Participant Information Sheet/Consent Form

Interventional Study - *Adult providing own consent*

Alfred Health

Title	Lignocaine in Gastroscopy Trial
Short Title	LIG Trial
HREC Reference Number	HREC/58991/Alfred-2019
Project Number	662/19
Principal Investigator:	Prof Paul Myles
Contact Investigator:	Dr Olivia Leahy
Associate Investigator(s)	Dr Max McCartney, Dr Jennifer Preddy, Dr Myat Thant Aung, Dr Andrew Melville, Ms Sophia Wallace, A/P Gregor Brown.
Location	Alfred 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 undergoing a gastroscopy procedure. The research project involves the use of a common local anaesthetic – lignocaine. We aim to see if lignocaine will improve the safety, gastroscopy conditions during the procedure, recovery from the sedation used during the gastroscopy and your perceived level of comfort after the procedure.

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?

Gastroscopies are generally carried out under sedation (sometimes called 'twilight anaesthesia'), with the aim of providing amnesia and comfort during the procedure. Most anaesthetists will use the medication Propofol as the drug of choice to achieve these goals, however, there is considerable variety in other medications used with Propofol in clinical practice. Some use opioids or other sedatives to improve patient comfort and emergence from the sedation.

One of the commonly used additional medications is Lignocaine. Lignocaine is an approved local anaesthetic in Australia used in a variety of clinical situations. In this setting, lignocaine is used to provide pain relief and potentially reduce the amount medication required for sedation. The Therapeutic Goods Association of Australia has approved lignocaine for intravenous and regional anaesthesia.

The aim of this study is to ascertain if the use of lignocaine in gastroscopies provides

- Smooth and earlier wake up from the procedure
- Provide better operating conditions for the doctor performing the procedure
- Earlier discharge from recovery
- Less discomfort after the procedure

3 What does participation in this research involve?

You will be participating in a randomised controlled research project. We put people into groups and give each group a different treatment. To try to make sure the groups are the same, each participant is put into a group by chance (random).

In this project you will either be placed in the 'treatment group' or 'control group'. The 'control group' will only receive Propofol and 0.9% normal saline (which is given as standard practice for gastroscopies) at the beginning of the procedure. Propofol is routinely used during gastroscopy sedation (twilight anaesthesia) and normal saline (NaCl 0.9%) is very frequently given to flush the drug into your vein, it does not affect your level of sedation. If you are in the 'treatment group', the anaesthetist will administer Propofol and lignocaine, with a further dose at 20 minutes if your gastroscopy is still occurring, after a maximum of two doses, no further doses will be given. (The combined lignocaine doses will not exceed >3mg/kg.)

The study will continue until you are discharged from the post-anaesthesia recovery unit (PACU) where your time to discharge and level of perceived discomfort will be noted, and your hospital length of stay recorded. We will also review, at the end of the study period, whether you were re-admitted to hospital within 24 hours of your procedure to determine why this may have occurred as this would be rare and unanticipated.

The data we will collect will include: which drugs and doses you received during your procedure, the number of minutes it took before you woke after your procedure, the ease with which the doctor doing your gastroscopy felt they could insert the camera, your discomfort score after the procedure, observations of your vital signs during the case and after your procedure, your time to discharge home and whether you were re-admitted to The Alfred. We will also collect data relating to your risk of anaesthesia and medical comorbidities relevant to the study.

You will have a **one in two chance** of receiving lignocaine or a 0.9% normal saline.

You will be participating in a double-blind study. This means that neither you, nor your study doctor, will know which treatment you are receiving. You will otherwise receive the same care pre and post procedure, as someone not involved in the trial. However, in emergency circumstances your study doctor can find out which treatment you are receiving.

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.
Conditions in which you would not be eligible for the study would include;

- Previous history of allergy or adverse reaction to lignocaine
- Severe liver disease with significant abnormal liver function tests
- If you are pregnant or breast feeding as the Ethics Approval does not include this.
- Aged <18 years of age or >80 years of age
- After-hours or emergency gastroscopies
- If you are likely to require a breathing tube (intubation) for your procedure
- If you are likely to require opioids (strong pain killers) during your procedure
- Treating anaesthetist decides that you would not be appropriate

To monitor your safety, the anaesthetist will use all of the 'standard monitoring' regardless of which group you are in. An anaesthetist routinely measures/monitors your heart rate and rhythm (ECG), oxygen saturations (using a finger probe) and blood pressure (BP cuff on your arm), in addition to their observations of your level of comfort and sedation. The trial does not prevent or affect you from receiving extra monitoring if your anaesthetist believes it is required. The researchers will use the data collected from your anaesthetic record, particularly any details of an adverse event, on the rare occasion that they occur. If you return to hospital within 24 hours of your procedure unexpectedly, we would like to include the reason for this admission to ensure it is not a problem related to your gastroscopy.

4 What do I have to do?

You will not have to change or withhold any of your regular medications before and after the procedure, unless requested specifically by the treating team outside of this study. Nor are there any dietary restrictions.

5 Other relevant information about the research project

Registered practitioners of Alfred Health will conduct this trial at (the single site of) the Alfred Hospital. The trial will require approximately 100 in participants total. These participants will be divided into a 'control group' who will receive normal saline 0.9% and the 'treatment group' who will receive lignocaine. No further study is planned and your participation will only be required on the day of your gastroscopy until you leave the 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 Alfred 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 choose not to participate you will receive the standard care that is normally provided with gastroscopies.

Alternatives to lignocaine that are commonly used include sedatives e.g. midazolam or opioids e.g. fentanyl. 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, possible benefits may include easier insertion of the gastroscope during the procedure, less discomfort post gastroscopy and possibly faster time to discharge from recovery.

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

Gastroscopies are generally a very safe and low risk procedure.

Lignocaine is also very familiar, safe and well-known local anaesthestic used in a variety of clinical settings from administering nerve blocks to management of neuropathic pain.

However medical treatments often cause side effects. You may have none, some or all of the effects listed below, and they may be mild, moderate or severe.

The risks with this study involve the side effects associated with lignocaine. If you have any of these side effects, or are worried about them, talk with your study doctor. Your study doctor will also be looking out for side effects.

Some of the possible side effects of using lignocaine include:

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Hypersensitivity			
Rash Urticaria	Not common	Not severe	Few minutes
Anaphylaxis	Rare	Severe	Minutes – hours
Central Nervous System			
Perioral Tingling Tongue numbness Tinnitus (ringing in ear) Sleepiness/dizziness	Common	Not severe	Few minutes
Visual disturbances Drowsiness/light-headed/confusion Euphoria/hallucinations Speech disturbance (slurred speech)	Rare	Moderate	Few minutes

Reduced level of consciousness/coma Seizures/convulsions Respiratory Arrest	Rare	Severe	
Cardiovascular system			
Hypotension	Common	Not severe	Few seconds
Arrhythmias (irregular heart beat) - Bradycardia (slow beat) - Tachycardia (fast beat)	Rare	Severe	Few minutes
May decrease effectiveness of defibrillation	Rare	Severe	-

In the rare event that you do develop severe adverse effects due to participation in this study, subsequent investigations and management will be carried out by Alfred Health.

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?

It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments.

However, whilst you are participating in this research project, you will be able to take all of the medications or treatments you have been taking for your condition or for other reasons.

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 before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

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 drug/treatment being shown not to be effective

• The drug/treatment being shown to work and not need further testing

15 What happens when the research project ends?

This information sheet contains contact details from a representative of this study if you have queries or concerns.

Once we have reached the number of participants required for this study, we will analyse and process the data with the aim of publishing our findings in a peer-reviewed journal. This may take at least 6-12 months.

Part 2 How is the research project being conducted?

16 What will happen to information about me?

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.

You have the right to privacy and all information collected during this study is confidential to the extent permitted by the applicable laws and regulations. You will be assigned a unique number and will be identified only by this number. The medical information collected during this study will be transferred into the study database(s) and processed to allow the results of this study to be analysed and reported or published for scientific purposes.

Your identity will be kept confidential at all times. The data collected for the study may be viewed by members of the Research and Ethics Committee to check that the study is being carried out correctly. All staff have a duty of confidentiality to all research participants and nothing that could reveal your identity will be disclosed by these persons.

Information about you will be obtained from your health records held at this and possibly 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

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.

If you are not satisfied with how your personal information has been handled (as laid out in the Privacy Act, 1988), then you can make a complaint to the Office of the Australian Information Commissioner (OAIC). Please refer to http://www.oaic.gov.au/privacy/privacy-complaints for more information.

The research team is required to keep the study data indefinitely. The data will not be given to third parties and if it were shared, it would be de-identified and only done for research purposes or publication.

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 the Principal Investigator Prof. Paul Myles and Co-Investigators Drs Olivia Leahy, Myat Aung, Jennifer Preddy, Max McCartney and Andrew Melville. The feasibility of this study does not require additional funding at this stage. All work done for this trial is voluntary and investigators are not paid. The investigators have no conflicts of interest to disclose.

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 Alfred 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 9076 3176 or any of the following people:

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

Clinical contact person

Name	Dr Olivia Leahy
Position	Principal Investigators
Telephone	9076 3176
Email	*o.leahy@alfred.org.au*

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 (please quote project number 662/19):

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*Alfred Hospital Ethics Committee*
Position	HREC Executive Officer
Telephone	*9076 3619*
Email	*research@alfred.org.au*

Consent Form - *Adult providing own consent*

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Principal Investigator:	Prof Paul Myles
Contact Investigator:	Dr Olivia Leahy
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Location	Alfred Hospital
Local Project Number	662/19

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 Alfred 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.

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

See Note for Guidance on Good Clinical Practice CPMP/ICH/135/95 Section 4.8.9. A legally acceptable representative may be a witness*.

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.

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

Title	Lignocaine in Gastroscopy Trial
Short Title	LIG Trial
HREC Reference Number	HREC/58991/Alfred-2019
Principal Investigator Contact Investigator	Prof Paul Myles Dr Olivia Leahy
Associate Investigator(s)	Dr Max McCartney, Dr Jennifer Preddy, Dr Myat Thant Aung, Dr Andrew Melville, Ms Sophia Wallace, A/P Gregor Brown.
Location	Alfred Hospital
Local Project Number	662/19

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 Alfred Health.

Name of Participant (please print) _____

Signature _____ Date _____

In the event that the participant's decision to withdraw is communicated verbally, pleas 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.