



## Participant Information Sheet/Consent Form

**Interventional Study - Adult providing own consent**

Frankston Hospital

<b>Title</b>	<i>Efficacy of probiotic gargles in reducing post-operative complications in adult post tonsillectomy patients: A pilot double-blinded, randomised controlled trial (feasibility trial)</i>
<b>Short Title</b>	<i>Are probiotics useful post tonsillectomy? – a pilot study</i>
<b>Protocol Number</b>	4
<b>Project Sponsor</b>	Peninsula Health
<b>Coordinating Principal Investigator/ Principal Investigator</b>	<i>A/Prof David Hunter-Smith</i>
<b>Associate Investigator(s)</b>	<i>Dr Michael Nasserallah, Mr Nalaka De Silva, Prof Warren Rozen</i>
<b>Location</b>	Frankston Hospital

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### Part 1 What does my participation involve?

#### 1 Introduction

You are invited to take part in this research project. This is because you are scheduled to have tonsillectomy or adenotonsillectomy surgery at Frankston Hospital. The research project is testing a new treatment for post-operative recovery from tonsillectomy or adenotonsillectomy. The new treatment is called probiotic gargles.

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?**

The aim of this project is to see if using probiotics post tonsillectomy can reduce your pain and improve healing.

Post-surgical pain is the most common and incapacitating symptom that patients experience. Currently we use paracetamol and sometimes stronger medications (such as endone) to manage pain after surgery. However, these stronger medications have side effects and, despite their regular use, pain still remains a problem.

There is a theory that pain worsens by day 5 due to infection, as 'bad bugs' grow in the site where your tonsils have been removed, the tonsillar fossa. The presence of these 'bad bugs' can worsen your pain by causing inflammation. Many studies have looked at using antibiotics as a preventative method of reducing pain, however, no clinically consistent result has been demonstrated.

Probiotics ('good bugs') are "live microorganisms which when administered in adequate amounts confer a health benefit on the host" according to the World Health Organisation (WHO). The probiotic we are using has an organism called *Streptococcus salivarius K12*, which has shown to prevent 'bad bugs' from growing, reduce inflammation and prevent bad breath (halitosis).

If probiotics are found useful, they may reduce your pain and reduce your requirement of stronger analgesic medications post-surgery, thereby providing you a better recovery. Additionally, if this probiotic is found to be useful then it may be used for further research in other inflammatory conditions.

The probiotic is called *Streptococcus salivarius K12*, which is approved in Australia to maintain/support ear health in children, maintain/support mouth flora, oral health, and oral mucous membrane health and reduce symptoms of tonsillitis. However, it is not approved to treat post-operative recovery of tonsillectomy or adenotonsillectomy. Therefore, it is an experimental treatment for post-operative recovery of tonsillectomy or adenotonsillectomy. This means that it must be tested to see if it is an effective treatment for post-operative recovery of tonsillectomy or adenotonsillectomy.

The results of this research will be used by the study doctor Michael Nasserallah to obtain a Masters of Surgery degree.

This research has been initiated by the study doctor, Dr Michael Nasserallah and Mr Nalaka De Silva.

This research has been funded by Peninsula health and is supported by Central Clinical School at Peninsula, who has offered to donate funds to purchase the probiotic sample and placebo treatment for each trial participant but are not involved in study design or conduct.

## **3 What does participation in this research involve?**

If you decide to take part in the research project, first you will be given a questionnaire asking about your medical history and this will determine if you are eligible to take part. Completing the questionnaire will take approximately 5minutes of your time.



If the screening questionnaire shows that you are suitable, then you will be able to start the research project. If the screening questionnaire shows that you cannot be in the research project, the research coordinator will discuss other options with you.

As a participant in this research, you will need to commit to doing the following:

- Read this form prior to coming to surgery
- Sign this form as a method of providing consent to participate in this trial
- Complete a daily pain diary (electronic questionnaire/survey sent to participants via email or phone daily or hard copy) for the 14 days after your surgery which rates your pain at rest, while drinking and while eating throughout the day. You will also document if you had any nausea, vomiting, diarrhoea, or bleeding. These may occur following surgery, irrespective of gargle or contents of gargle.
- Use the trial medication gargle as prescribed. This trial pack will be provided by the pharmacist at Frankston Hospital in a sealed envelope and they will know whether you have received placebo or the probiotic.
- Follow-up will be on Day 5 (via phone/in person), Day 14 after your operation in person and 4 weeks after your operation in person. In person follow-ups will be at the outpatient's department at Frankston Hospital
- At the end of trial (Day 14) you will need to bring the trial medication pack with you
- Follow up visits will be organised at Frankston Hospital outpatients clinic
- If you require an interpreter please inform Dr Michael Nasserallah so that the necessary arrangements can be made prior to your appointments

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.

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 double-blind study. This means that neither you nor your study doctor will know which treatment you are receiving. However, in certain circumstances your study doctor can find out which treatment you are receiving.

To properly control the investigation, participants will be assigned to one of two study groups (treatment and placebo treatment). A placebo is a medication with no active ingredients or a procedure without any medical benefit. It looks like the real thing but is not.

The hospital pharmacists have generated a randomly ordered list of treatment orders and have packaged the placebo and probiotic gargles so the study doctors and participants will not know which treatment is being used, only the hospital pharmacists. The packaging will however list all the ingredients so you can check for allergies. At this time, the study doctors will only know participants are in group 1 or 2. Even the statistical analysis of results will be performed knowing only group 1 versus group 2. This is done to avoid bias. After data collection and analysis is complete, the pharmacists will reveal which group is the placebo and which the probiotic treatment group.

The dose of probiotic is: *S. salivarius* K12 – 125 million Colony Forming Units/dose. The powder will come with a serving spoon equivalent to ¼ of teaspoon. The dose is 2 spoons (or ½ teaspoon) and this is dissolved in 20mls of warm water and gargled for 30 seconds then swallowed. The placebo is the same amount (1/2 teaspoon or 2 scoops) of isomalt powder. This is taken in the



same way as the probiotic. The gargle (probiotic or placebo) is performed 4 times a day, for 14 days ideally after brushing teeth and before meals, starting 24 hours following surgery.

There are no costs associated with participating in this research project, nor will you be paid.

The research will be monitored by the Peninsula Health Human Research Ethics Committee, to whom we submit annual study reports.

#### **4 What do I have to do?**

Lifestyle instructions or restrictions are as standard protocol post-tonsillectomy:

- eat rough and/or textured foods regularly,
- avoid exercise, strenuous activity or donating blood for 2 weeks,
- have medications including gargles approximately 1 hour prior to meals.
- Postoperative pain relief is otherwise as usual. You will be given a prescription for Panadol and endone. Take as instructed.
- Non-Steroidal Anti-inflammatory Drugs (NSAIDs) are not to be used for duration of trial
- Antibiotics should not be used unless patients are admitted with severe pain, dehydration or secondary haemorrhage. If antibiotics are prescribed by the general practitioner then you will be withdrawn from trial treatment.
- Each participant should discuss taking their regular medication with the study doctor

The researcher will ask you if you have any conditions or allergies that may prevent you from participating in the trial.

The responsibilities and commitment of the participants are described above, and need to be undertaken in accordance with the instructions provided.

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

This trial will aim to have 30 patients. There will be two groups: one group will receive the probiotic gargle and the other will receive a placebo gargle.

All participants will have the same surgeon (Dr Michael Nasserallah) and will have the same operative technique.

All participants will be from Frankston Hospital waiting list.

#### **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 Peninsula 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. The alternative is to have your tonsillectomy or adenotonsillectomy post-operative care as standard (no gargles and no documenting pain on eating, drinking and resting). 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 reduced pain and reduced risk of side effects from stronger pain-killers.

## 9 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, and they may be mild, moderate or severe. 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.

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.

Many side effects go away shortly after treatment ends. However, sometimes side effects can be serious, long lasting or permanent. If a severe side effect or reaction occurs, your study doctor may need to stop your treatment. Your study doctor will discuss the best way of managing any side effects with you.

Side Effect	How often is it likely to occur?	How severe might it be?	How long might it last?
Diarrhoea	unlikely	likely to be mild	Less than a day
Abdominal pain	unlikely	likely to be mild	Less than a day
Dyspepsia	unlikely	likely to be mild	Less than a day
Nausea	unlikely	likely to be mild	Less than a day

In the event of bleeding from the post tonsillectomy site: gargle with some ice water (preferably with ice cubes) and it should settle down. If bleeding persists, please go to the Emergency Department of Frankston Hospital / any nearest hospital and inform the doctors there that you are in a post tonsillectomy trial and to ask them to call Frankston Hospital and be put through to Dr Michael Nasserallah, ENT Registrar.

If you become upset or distressed as a result of your participation in the research, the study doctor will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research project team. This counselling will be provided free of charge.



### **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?**

Whilst you are participating in this research project, you may not be able to take some or all of the medications or treatments you have been taking for your condition or for other reasons. 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. You should also tell your study doctor about any changes to these during your participation in the research project. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the research project.

It may also be necessary for you to take medication during or after the research project to address side effects or symptoms that you may have. You may need to pay for these medications and so it is important that you ask your doctor about this possibility.

### **13 What if I withdraw from this research project?**

If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you stop being in the study early, the study doctor or study staff may ask you some questions about being in the study. To help you leave the study safely, the study doctor may ask you to participate in a final visit. However, you will not be required to attend any further visits and may continue to receive appropriate follow up treatment and care from your regular doctor.

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.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the 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 drug/treatment/device being shown not to be effective
- The drug/treatment/device being shown to work and not need further testing
- Decisions made in the commercial interests of the sponsor or by local regulatory/health authorities.

#### **15 What happens when the research project ends?**

When the project ends we hope to publish the results in a medical journal and present it at a medical conference. All data presented will be anonymous. If you would like to receive a copy of the results please inform the Principal Investigator.

### **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 research staff collecting and using personal information about you for the research study. All study records are kept for a minimum of 15 years. Any information obtained in connection with this research study that can identify you will remain confidential. Your information will only be used for the purpose of this research study 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 study.

It is anticipated that the results of this research study 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.

Information about your participation in this research study 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 doctor if you would like to access your information.

The information you record on your data sheet will be entered into a computer spreadsheet and then analysed. This means during data collection, electronic data is identifiable, to ensure accurate data collection and management. Once data collection is complete and data checked for duplicates and accuracy, identifiers will be permanently removed. This means, your name and any details that identify you will be removed at this stage and your information will be given a unique study code. Data is thereafter permanently non-identifiable.

Your data sheets/diaries will be stored in a locked filing cabinet in the Department of Surgery, which can only be accessed by the Department of Surgery Research Co-ordinator, until data collection and analysis has been completed. At this time, all paperwork will be archived the Peninsula Health secure data archival system for 15 years after publication in accordance with the law. After this time, data sheets will be disposed of by the Peninsula Health sensitive paperwork disposal system. Likewise, all electronic files will be password protected and stored



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only on secure password protected Peninsula Health server. 15 years after publication, all electronic files will be permanently deleted.

You are being asked to provide consent to the use of your data for this project only.

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 Dr Michael Nasserallah and other ENT surgeons in the department of Surgery, Frankston Hospital.

Monash University may benefit financially from this research project if, for example, the project assists Monash University to obtain approval for a new application for the probiotic gargle.

If knowledge acquired through this research leads to discoveries that are of commercial value to Monash University, the study doctors or their institutions, there will be no financial benefit to you or your family from these discoveries.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

## **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 Peninsula 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.

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## 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 please ring Hospital Switchboard 9784 7777 and ask for Dr Michael Nasserallah.

### Clinical contact person

Name	Dr Michael Nasserallah
Position	ENT Registrar
Telephone	Hospital switchboard 9784 7777 and ask for Dr Nasserallah
Email	mnasserallah@phcn.vic.gov.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:

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

Name	Ms Lee-Anne Clavarino
Position	Manager Office for Research
Telephone	03 97842679
Email	ResearchEthics@phcn.vic.gov.au

## Consent Form - Adult providing own consent

**Title** *Efficacy of probiotic gargles in reducing post-operative complications in adult post tonsillectomy patients: A pilot double-blinded, randomised controlled trial (feasibility trial)*

**Short Title** *Are probiotics useful post tonsillectomy? – a pilot study*

**Protocol Number** 4

**Project Sponsor** Peninsula Health

**Coordinating Principal Investigator/  
Principal Investigator** A/Professor David Hunter-Smith

**Associate Investigator(s)** *Dr Michael Nasserallah, Mr Nalaka De Silva,  
Prof Warren Rozen*

**Location** Frankston Hospital

### **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 Peninsula 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, witness \\* required](#)  
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. 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) _____
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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.

I understand that, if I decide to discontinue the study treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

Name of Participant (please print) \_\_\_\_\_  
Signature \_\_\_\_\_ Date \_\_\_\_\_

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. 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.

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.

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

**Title** *Efficacy of probiotic gargles in reducing post-operative complications in adult post tonsillectomy patients: A pilot double-blinded, randomised controlled trial (feasibility trial)*

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Principal Investigator** A/Professor David Hunter-Smith

**Associate Investigator(s)** *Dr Michael Nasserallah, Mr Nalaka De Silva,  
Prof Warren Rozen*

**Location** Frankston 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 Frankston 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.

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### **Declaration by Study Doctor/Senior Researcher<sup>†</sup>**

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 <sup>†</sup> (please print) _____
Signature _____ Date _____

<sup>†</sup> 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.