Participant Information Sheet

Title	Enhanced Recovery After Surgery: Feasibility of Pre-operative Carbohydrate Loading in Patients Undergoing Major Head and Neck Cancer Surgery with Free Flap Reconstruction
Principle Investigator	Merran Findlay Executive Research Lead – Cancer Nutrition, Sydney Local Health District Oncology Dietetics Clinical Research Fellow, Chris O'Brien Lifehouse Email: Merran.Findlay@health.nsw.gov.au Mobile: 0411 779 420
Location	Chris O'Brien Lifehouse Missenden Road CAMPERDOWN NSW 2050 AUSTRALIA

Introduction

You are invited to take part in a research study that aims to improve the nutritional care of people having surgery for head and neck cancer at Chris O'Brien Lifehouse. The aim of this study is to test whether a carbohydrate rich drink can improve your wellbeing prior and following surgery. The drink used is called Nutricia PreOp®.

This Participant Information Sheet and Consent Form tell you about the study and explain the tests 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 do not 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 or friend or your local doctor.

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

If you agree to take part in the study, you will be asked to sign the consent form. By signing it, you are telling us that you:

- Understand what you have read
- Consent to take part in the study
- 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 Form to keep.

What is the purpose of this research?

The purpose of this study is to investigate whether consuming a carbohydrate rich drink prior to surgery improves your wellbeing before and after your operation. While fasting before surgery has been traditional practice, there is good evidence that providing carbohydrate rich drinks before surgery is better than avoiding fluids altogether.

A number of studies have shown that it is actually safe to drink water or carbohydrate rich drinks up to two hours before surgery. These studies suggest that patients feel less nauseous or hungry prior to the surgery and that the risks of infection may be lower with carbohydrate-rich drinks. Because the studies that have been performed have not specifically focussed on patients with head and neck cancer, we would like to undertake a similar study to establish the benefits and acceptability of pre-operative carbohydrate drinks in patients with head and neck cancers.

This research has been initiated by Merran Findlay, Executive Research Lead – Cancer Nutrition, Sydney Local Health District and Oncology Dietetics Clinical Research Fellow, Chris O'Brien Lifehouse in collaboration with Professor Jonathan Clark, Director of Research for Head and Neck Cancer Surgery at Chris O'Brien Lifehouse. The study has funding support from the Australia and New Zealand Head and Neck Cancer Society Research Foundation.

Study Procedures

Following the pre-admission clinic visit if you agree to participate in this study, you will be asked to sign the Participant Consent Form. The study is a prospective cohort study which means that once you have agreed to participate you will receive either standard care or the intervention drink.

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. For this study, half of the participants will receive standard care which is to remain nil by mouth for 4-6 hours prior to surgery. The other half of the participants will be given carbohydrate drinks to take at two time points in the few hours before your operation.

In either case you will be asked before and after your operation a few wellbeing measure questions. These are basic questions to help assess how you are feeling at the time. Blood samples will be taken on induction and on days 1 and 7 following surgery and will be processed as part of routine lab procedures. They will not be stored or "banked."

Assessment of wellbeing measures (using relevant visual analogue scales) will take place prior to induction and on the first day after surgery. These measures will be used to assess your wellbeing (for example thirst, hunger, etc).

Participants receiving the intervention will take 800mL Nutricia Pre-Op® carbohydrate drink the evening before surgery (8pm) and then 400mL on admission to Day Procedure Unit (TPU) or 2 hours before expected surgery, whichever is later.

The duration of participant involvement in this study is 2 days and no follow up is required. Finally, the researchers would like to have access to your medical record to obtain information relevant to this study.

Risks
All medical procedures involve some risk of injury. In addition, there may be risks associated with this study that are presently unknown or unforeseeable. In spite of all reasonable precautions, you might develop medical complications from participating in this study.

According to the evidence available from previous studies there are no known additional significant risks associated with this study. It is possible that you might get some bruising from the additional blood test we will ask you to take and you might find answering the questions slightly inconvenient.

There is a theoretical risk that drinking fluid closer to the time of your anaesthetic increases your risk associated with the anaesthetic but this has not been seen in many prior studies using preoperative drinks. As anaesthetic relaxes the muscles in your digestive tract and airway, if your stomach contains any food or drink there is a risk of vomiting, regurgitation or aspiration. There may also be risks associated with this trial that are presently unknown or unforeseeable. Caution should be taken with participants with diabetes as carbohydrate rich fluids may decrease post-operative insulin resistance.

Benefits
While we intend that this research study furthers medical knowledge and may improve the care provided to patients with head and neck cancer in the future, it may not be of direct benefit to you. However, possible benefits may include improved well-being, reduced nausea and hunger prior to surgery and moderate metabolic responses to surgery, lower risk of infection post-surgery and decreased post-operative insulin resistance.

What if new information arises during this study?
Sometimes during the course of a study, 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 study. 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 study 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 study. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

Can I have other treatments during this study?
Whilst you are participating in this study, 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 study. Your study doctor should also explain to you which treatments or medications need to be stopped for the time you are involved in the study.

Costs
There are no additional costs associated with participating in this study, nor will you be paid.

Voluntary Participation
Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason. Whatever your decision, please be assured that it will not affect the provision of treatment in any way nor your relationship with care staff. If you do decide to participate, a research officer will record your consent to participate and collect your information. Your decision to participate or not participate will not be known by any health professional involved in your care.

What if I withdraw from the study?
If you decide to withdraw from the study, 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.

In the event that you decide to withdraw while you are at home, do not consume any drinks you have been provided. If you have consumed any drinks prior to your decision please ensure this is recorded in the Dosing Diary you are provided and do not consume any more drinks. On the day of your surgery please bring all unconsumed drinks with you and notify a member of the study team that you would like to withdraw from the study. If you do withdraw your consent during the study, 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 study can be measured properly and to comply with law.

Confidentiality
Your decision to participate and all information collected from you for the study will be treated confidentially. All information collected during the study will be confidential and won't be shared with any health professional involved with your care. The study results may be presented in reports, at a conference, or in a scientific publication, but participants will not be identifiable.

Further Information
When you have read this information, Merran Findlay (Research Lead) will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact her on 0411779420 or Merran.Findlay@health.nsw.gov.au This information sheet is for you to keep.

Ethics Approval and Complaints
This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number XXX-XXXX.

CONSENT FORM

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Declaration by Participant

I have read and understand the Participant Information Sheet. I have had the opportunity to ask questions and am satisfied with the answers I have received.

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

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

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

In addition, I consent to the storage and use of blood samples taken from as described in the relevant section of the Participant Information Sheet for this specific study.

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

Name of Participant (please print) _____

Signature _____ Date _____

Declaration by Senior Researcher

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

Name of Senior Researcher (please print) _____

Signature _____ Date _____

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