**PARTICIPANT INFORMATION SHEET**

**&**

**INFORMED CONSENT FORM**

**STUDY TITLE**: Foley Catheter Insertion into Defunctioning leostomy

To reduce Postoperative Ileus after Major Colorectal Surgery

 **LAY TITLE:** Foley Catheter study

**PRINCIPAL INVESTIGATOR:** Dr.Suheelan Kulasegaran ( MBChB, PG DipSurg Anat)

**SUB INVESTIGATOR:** Dr. Carolyn Vasey (MBChB, FRCS)

**INTRODUCTION**

All patients having bowel surgery with a loop ileostomy will be offered the opportunity to participate in this research study. The aim of the study is to find out whether or not a Foley catheter placed in the stoma during surgery will help reduce post-operative swelling. It is believed that this method may help prevent occurrences of an ileus after surgery. An ileus is a common complication of bowel surgery, where the bowel can get blocked causing low or no output from the stoma; this can cause nausea and discomfort.

The study will take place at North Shore Hospital and aims to recruit 50 participants. Whether or not you choose to take part is your choice. If you choose not to take part, you do not have to give a reason, and it will not affect the care you receive in any way, nor the timing of your surgery. Before you make a decision you may want to talk about the study with other people, such as family, Whānau, friends or other healthcare providers.

This information sheet explains why we are doing the study, what participation would involve and what the benefits and risks to you might be. Your surgeon or research nurse can explain any words in this information sheet that you do not understand and answer any questions or concerns you may have. Personal benefits to you may or may not result from taking part in the study, but knowledge may be gained from your participation that will benefit others.

**CULTURAL SUPPORT:**

If you require Māori cultural supports talk to your Whānau in the first instance. Alternatively you may contact the administrator for He Kamaka Waiora (Māori Health Team) by telephoning 09 486 8324 ext. 2324

**QUESTIONS AND COMPLAINTS:**

If you have any questions or complaints about the study you may contact the Auckland and Waitematā District Health Boards Maori Research Committee or Maori Research Advisor by telephoning 09 4868920 ext 3204

If you would like other cultural support please contact:

Asian health support service at North Shore Hospital 4868920 ext 2314 or ask your research nurse to contact the appropriate service on your behalf.

**WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE ANY CONCERNS?**

If you have any queries or concerns regarding your rights as a participant in this study, you can contact an independent Health and Disability advocate. This is a free service provided under the Health and Disability Commissioner Act. Telephone: (NZ wide) 0800 555 050

Free fax (NZ wide) 0800 2787 7678 (0800 2 SUPPORT) Email (NZ wide): advocacy @hdc.org.nz

Contact details for your research nurse and other study personnel are listed at the end of this document.

**WHO PAYS FOR THE STUDY?**

This research study is being structured and paid for by the colorectal research department at North Shore Hospital. You will not be paid for participating in this study, however, reasonable travel costs will be covered by the colorectal research department for any extra visits required that are specifically related to study treatment and are not routinely standard practice.

**CONFIDENTIALITY:**

All study information will be kept in the secure surgical research office, accessible to research personnel only. Participants will be de-identified and given a unique study number. Electronical data sheets and study information are maintained on the hospital intranet but are only accessible to research personnel with the password.

Sections of your medical records may be looked at by responsible individuals conducting the study, representatives of regulatory authorities or Northern B Regional Ethics Committee for the purposes of analysing the results or checking that the study is being carried out correctly. This study is confidential therefore, should you decide to participate no material which could identify you will be used in any reports on this study. You have the right to access information about you collected as part of the study. The study information will be archived once the study is over and could be kept for up to 15 years.

**WHAT WILL MY PARTICIPATION INVOLVE?**

* Informed Consent Process:

Before your surgery you will have opportunities at your out patients clinic appointments, and by contact with your research nurse, to discuss the study. Should you choose to participate written informed consent will be required once you have had enough time to make a decision. This will occur on the morning of your surgery, where you will again have the opportunity to discuss the study procedure again.

* Intra-operative Procedure:

Whether you take part in this study or not the pre-operative procedures are standard. In surgery a sealed envelope will be opened which will decide whether you will have the Foley catheter inserted (this is called the treatment arm) or whether you will not (this is called standard of care). This process is called randomization and means the procedure you receive is decided by chance, this takes away any possibility of bias in the distributing procedure. If you are randomized to standard of care your surgery will be no different. If you are randomized to treatment a Foley catheter will be inserted into the stoma during surgery. The catheter is a thin hollow rubbery tube, when it is inserted a tiny balloon at the tip is filled with water, this holds the catheter in place.

 

* After Surgery:

Participation in this study will not alter your usual post-operative care. The Research Nurse will visit you on the ward to document your progress. If you have a Foley catheter inserted there is a chance it may fall out, if this happens it will be reinserted up to a maximum of 3 times. This is done in a lying position on the ward in bed. Lubricant is applied to the catheter tip by the principle investigator or another doctor involved in the study. The catheter is then gently re-inserted and is usually a well-tolerated procedure.

Participants in this study will have routine surgical follow up in the outpatient department as normally determined by their clinical need. Extra follow up appointments are not required specifically for the purposes of this study. Your GP will be informed of your participation and the results of the study findings will be made available to you by letter once complete.

**ETHICAL APPROVAL:**

This study was granted Ethical approval on the ………... by the Northern B Health and Disability Ethics Committee. Reference number: …………..

This approval covers the procedures outlined in this protocol. Any significant amendments to this protocol require approval from a New Zealand Health and Disability Ethics Committee.

**COMPENSATION:**

If you were injured in this study, which is unlikely, you would be eligible for compensation from ACC just as you would be if you were injured in an accident at home or at work. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If you claim was accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won’t affect your cover.

**SAFETY & RISKS:**

Your surgery is a scheduled surgery, the possible risks and discomforts that may be expected include any of the standard risks and discomforts associated with colorectal surgery. Potential surgical risks will be explained by your surgeon before surgery as usual standard practice.

**KEY CONTACT DETAILS:**

Name: Dr Dr.Suheelan Kulasegaran

Title: Principal Investigator

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Name: Dr. Carolyn Vassey

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Title: Research Nurse Coordinator, Colorectal Unit, NSH

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**INFORMED CONSENT FORM**

**STUDY TITLE**: Foley Catheter study

**FULL PROJECT TITLE:** Foley Catheter Insertion into Defunctioning leostomy To reduce Postoperative Ileus after Major Colorectal Surgery

 **ETHICS APPROVAL NUMBER: ……………………………………….**

**INVESTIGATOR NAME:** Dr. Suheelan Kulasegaran ( MBChB, PG DipSurg Anat). North Shore Hospital, Takapuna

**PATIENT ONLY TO COMPLETE:**

**REQUEST FOR INTERPRETER**

|  |  |  |  |
| --- | --- | --- | --- |
| Deaf and hearing impaired | I wish to have a NZ sign language interpreter. | Yes | No |
| English | I wish to have an interpreter. | Yes | No |
| Maori | E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero. | Ae | Kao |
| Samoan | Ou te mana’o ia i ai se fa’amatala upu. | Ioe | Leai |
| Tongan | Oku ou fiema’u ha fakatonulea. | Io | Ikai |
| Cook Island | Ka inangaro au i tetai tangata uri reo. | Ae | Kare |
| Niuean | Fia manako au ke fakaaoga e taha tagata fakahokohoko kupu. | E | Nakai |

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, *(please print your name clearly and tick the boxes below to acknowledge what you are consenting to)*

* Have read the participant information sheet, version 1, dated May, 2015 about the Foley Catheter Study and have had the opportunity to ask questions and discuss the study and I am satisfied with the answers I have been given
* Have had the opportunity to seek support from family, Whanau, friends and relevant healthcare workers to guide my decision as I see appropriate
* Understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing health care
* Understand that my participation in this study is confidential and no material which could identify me will be used in any reports on this study. My study information will be maintained securely for a period of up to 15 years
* Understand that sections of any of my medical records may be looked at by responsible individuals conducting the study, representatives of regulatory authorities or Northern b Regional Ethics Committee for the purposes of analyzing the results or checking that the study has been carried out correctly
* Agree to my GP being informed of my participation in this study and the results of my participation and that the results of the study will be made available to me once it is complete
* Understand that I am undergoing scheduled surgery, the possible risks and discomforts that may be expected include any of the standard risks and discomforts associated with colorectal surgery. Potential surgical risks will be explained to me by my surgeon before surgery as usual standard practice

**Patient Signature**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**INVESTIGATOR ONLY TO COMPLETE:**

I, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ declare that my signature below is a legal binding document and demonstrates the following:

* I have given the participant this form and explained the study to them
* I am satisfied that the participant has a good understanding of the study and the procedures
* I have given the participant the chance to ask questions and have answered them to the best of my ability
* This participant meets all the inclusion and exclusion criteria of the study
* This consent process has included a registered interpreter as necessary

**Investigator name: ­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­­**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Investigator Signature: ­­­­­­­­­­­­­­­­­­­­­**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date**: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**INTERPRETER ONLY TO COMPLETE:**

**Interpreter name:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Registered Company:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Interpreter signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_