Participant Information Sheet/Consent Form

QEII Jubilee Hospital

Title	*Assessing the safety of routine snare tip soft coagulation (STSC) in patients undergoing cold endoscopic mucosal resection for large polyps during colonoscopy*
Short Title	*Cold STSC*
Protocol Number	
Project Sponsor	*n/a*
Coordinating Principal Investigator/ Principal Investigator	*Dr Nicholas Tutticci*
Location	*QEII Jubilee Hospital*

Part 1 What does participation involve?

1 Introduction

You are invited to take part in this research project because you may have a colonic polyp greater than 15mm in diameter. The research project is testing whether routine application of *snare tip soft coagulation* is safe and should be implemented as standard of care.

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 you can 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 do not have to. You will receive the best possible care whether or not they take part.

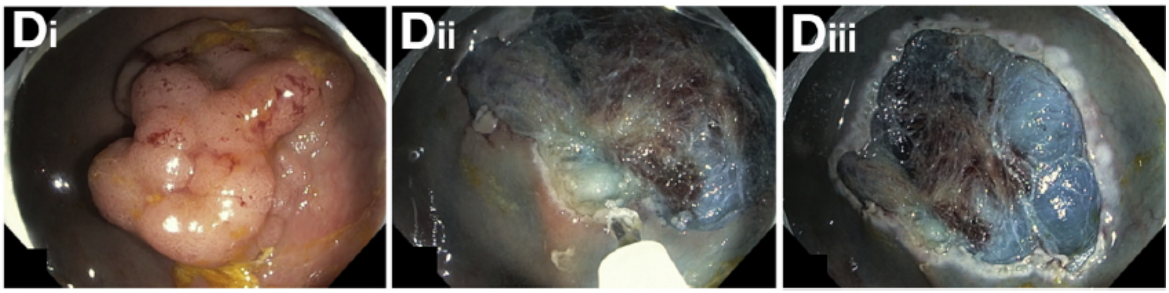
If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
• Understand what you have read
• Consent to taking part in the research project
• Consent to having the tests and treatments that are described
• Consent 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?

Colorectal cancer (CRC) is a major cause of cancer related morbidity and death in Australia. In 2018, CRC was the 3rd most common cancer diagnosed and the 2nd most common cause of cancer-related death. The majority of CRCs arise from polyps and the removal of polyps at colonoscopy reduces the risk of cancer.

Large polyps are routinely removed using a technique called endoscopic mucosal resection (EMR), which involves injection of a blue solution to lift the polyp from the bowel wall before removal with a snare. EMR can be performed "hot", with electrocautery, or "cold" without. One of the limitations of EMR is that small amounts of polyp tissue can be left behind which is called residual. From this the polyp can "grow back". Residual occurs in 8-20% of EMR cases. For hot EMR, applying STSC to the rim of the polypectomy site reduces the rate of residual significantly. These studies have shown STSC to be safe and effective however STSC application to the rim of cold EMR has not yet been researched.



Above: examples of a polyp prior to removal (Di) and after removal (Dii). The margins have been treated with STSC after complete removal of the polyp (Diii); pictures copied from *Klein et al Gastroenterology 2019;156:604–613.*

3 What does participation in this research involve?

Patients who are booked to have an elective outpatient colonoscopy are invited to participate in this study. If a large sessile polyp (greater than 15mm) is identified and your doctor removes it with cold EMR, you will then be randomised to one of two treatment arms. This occurs during the colonoscopy and patients will therefore be blinded to which treatment they received. The proceduralist will be aware of which treatment arm the patient randomised to.

The two treatment arms are:

1) STSC arm – thermal ablation of the margins of the resection defect
2) Control arm – standard treatment, which involves no further therapy

Post-procedural care in recovery and following discharge from hospital will be identical in both treatment arms. Routine observations and any additional treatment (such as pain relief) will be recorded. Patients will also receive a 30-day questionnaire as per department policy for routine follow-up. A surveillance colonoscopy 6 months after the initial colonoscopy will be arranged to assess the polyp site for residual or recurrent adenoma in all patients; this is the current recommended surveillance interval as per NHMRC guidelines.

There will be no cost or reimbursement to the patient in this study.

4 What does the participant have to do?

You will not need to undertake any additional steps for your colonoscopy and follow up if you agree to enter the study or not.

5 Does the participant 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 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 will not affect your routine treatment, your relationship with those treating them, or your relationship with the QEII Jubilee Hospital.

6 What are the alternatives to participation?

If you do not participate in this study, you will undergo your colonoscopy as per usual practice.

7 What are the possible benefits of taking part?

This study aims to see whether routine STSC will reduce the rates of residual or recurrent adenomas. If results are positive, it may reduce the need for repeated colonoscopies patients require for surveillance, which will also improve the overall healthcare burden.

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

STSC is shown to be safe; it is frequently used endoscopically to treat and control bleeding. Therefore, the risks associated with cold EMR of a large polyp (with or without subsequent STSC) are as documented in the standard colonoscopy consent form: up to 1% risk of serious bleeding (the majority of which can be controlled during the colonoscopy) and 0.1% risk of deep injury including a bowel perforation.

9 What will happen to the participant's test samples?

Tissue obtained during the colonoscopy will be sent to pathology and results will be followed up by the proceduralist as per standard care.

10 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, the 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, the study doctor will make arrangements for their 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, the study doctor might consider it to be in your best interests to be withdrawn from the research project. If this happens, the doctor will explain the reasons and arrange for the participant's regular health care to continue.

11 Can the participant have other treatments during this research project?

No; the treatments available following polyp resection will be limited to standard of care (the control group) and STSC (the treatment group). However, this should not affect any other aspects of your healthcare or other health conditions.

12 What if I withdraw from this research project?

If you decide to withdraw from the project, please notify a member of the research team. This notice will allow that person or the research supervisor to further discuss any health risks or special requirements linked to withdrawing.

If you do withdraw, the study doctor and relevant study staff will not collect additional personal information from you and this will not be included in any future data analysis.

13 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 treatment being shown not to be effective
• The treatment being shown to work and not need further testing

14 What happens when the research project ends?

Data collection for the research project is anticipated to end when enough patients are recruited to the study. This will not affect your follow up colonoscopies or subsequent overall management.

Part 2 How is the research project being conducted?

16 What will happen to information about the participant?

Data collected will be coded and kept in a locked room at the QEII Hospital. Patients will be de-identified. This data is intended to be published in a relevant medical journal. By signing the consent form you consent to the study doctor and relevant research staff collecting and using your healthcare information for the research project. Clinical data will be collected through your medical records on the electronic medical records system (ieMR). Data collected will include your medical history, details regarding the colonoscopy and which treatment was applied, polyp histology, any potential complications and the outcomes from subsequent colonoscopies (ie. whether any residual polyp was found).

Any information obtained in connection with this research project that can identify you will remain confidential.

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 project is being conducted by the QEII Gastroenterology Department without additional funding. There are no financial declarations.

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).

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 the participant has any medical problems which may be related to their involvement in the project (for example, any side effects), you can contact the QEII Endoscopy Unit on 07 3182 4500.

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:

This person should be someone independent of the research, such as the Executive Officer of the reviewing HREC that approved the project (if a multi-centre clinical trial). Contact your local HREC administrator (single site trial) for the requirements at your institution.

Reviewing HREC approving this research and HREC Executive Officer details

Reviewing HREC name	*Metro South Hospital and Health Service Human Research Ethics Committee (EC00167)*
HREC Executive Officer	*MSH HREC Coordinator*
Telephone	*07 3443 8047*
Email	*MSH-Ethics@health.qld.gov.au*

Consent Form – Person Responsible

Title	*Assessing the safety of routine snare tip soft coagulation (STSC) in patients undergoing cold endoscopic mucosal resection for large polyps during colonoscopy*
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Coordinating Principal Investigator/ Principal Investigator	*Dr Nicholas Tutticci*
Location	*QEII Jubilee Hospital*

Declaration by Person Responsible

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 have had an opportunity to ask questions and I am satisfied with the answers I have received.

I believe that the participation in this study is not contrary to my best interests.

I freely agree to participating in this research project as described and understand that I am free to withdraw at any time during the research project without affecting my/their future health care.

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

I give permission for the participant's doctors, other health professionals, hospitals or laboratories outside this hospital to release information to QEII Jubilee Hospital concerning my treatment for the purposes of this research project. I understand that such information will remain confidential.

Name of Participant (please print) _____

Signature _____ Date _____

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 person responsible 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 – Person Responsible

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Coordinating Principal Investigator/ Principal Investigator	*Dr Nicholas Tutticci*
Associate Investigator(s)	
Location	*QEII Jubilee Hospital*

Declaration by Person Responsible

I wish to withdraw from taking part in the above research project and understand that such withdrawal will not affect my routine treatment, relationship with those treating them or their relationship with QEII Jubilee Hospital.

Name of Participant (please print)

Signature _____ Date _____

Name of Study Doctor/
Senior Researcher (please print) _____

Signature _____ Date _____

Note: All parties signing the consent section must date their own signature.