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**PARTICIPANT INFORMATION AND CONSENT FORM**

**Project title:** The effect of Polyethylene Glycol on constipation after benign gynaecological laparoscopy: A double-blinded randomised placebo-controlled trial

**Protocol Number:**  Version 3.0

**Principle Investigator:** Dr Avelyn Wong

**Associate Investigators:**  A/Prof Martin Healey, Dr Paul Berlund, Dr Charlotte Reddington, Dr Claudia Cheng, Dr Michal Amir, Dr Helen McNamara

**Site:** Royal Women’s Hospital, Parkville

1. Your Consent

You are invited to take part in this research project because you are planning to have surgery at The Royal Women’s Hospital. The research project is looking at whether the use of a common laxative after surgery prevents constipation.

This Participant Information contains detailed information about the research project. Its purpose is to explain to you as openly and clearly as possible all the procedures involved in this project before you decide whether or not to take part in it.

Please read this Participant Information carefully. Feel free to ask questions about any information in the document. You may also wish to discuss the project with a relative or friend or your local health worker.

Participation in this project is entirely voluntary. Your care will not be disadvantaged in any way if you decide that you do not want to be a part of this project. You will receive the best possible care, whether or not you decide to be involved. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

Once you understand what the project is about and if you agree to take part in it, you will be asked to sign the Consent Form. By signing the Consent Form, you indicate that you

* understand the information
* consent to participate in the research project
* consent to the use of your information as described

You will be given a copy of the Participant Information and Consent Form to keep as a record.

2. What is the purpose of this research?

Constipation after abdominal surgery is common. There are many reasons for this including fasting before surgery, being less physically active after surgery and medications given to you during and after the surgery which may cause constipation.

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When present it can cause discomfort and distress to patients. It may lead to patients staying longer in hospital, seeking additional medical attention and experiencing more pain. Despite being a common problem, there is little evidence to guide clinicians and their patients on the best choice of laxative and how long to take medication to prevent constipation after surgery.

The purpose of this project is to look at whether short term use of a commonly used laxative reduces constipation after laparoscopic (keyhole) surgery for gynaecological reasons. We hope that the results of the study can be used to better manage constipation after surgery for patients in the future.

The scientific name of the laxative medication being used is called Polyethylene Glycol 3350 (also known as Macrogol). It is the main ingredient in laxative brands such as Movicol or Osmolax which are freely available over-the-counter. It is been approved in Australia for treatment of constipation by the Australia Federal Government, and is commonly used in children, adults and the elderly.

You are invited to participate in this research project because you are planning laparoscopic (keyhole) surgery at the Royal Women’s Hospital for a gynaecological reason.

The results of this research may be used in a publication in a medical journal.

3. What does participation in this research involve?

Participation in this project will involve about 20-30 minutes of your time, completing a total of 3 surveys, and taking a study medication for 7 days after your surgery.

This is a randomised controlled research project. Sometimes we do not know which treatment is most effective for treating a condition. To find out we put people into groups to compare if the active treatment is better than a placebo medication. A placebo medication is a medication with no active ingredients without any medical benefit.

This is a double-blinded study. This means that you, the participant, and the study doctor will not know which treatment you are receiving. However, in certain circumstances the study doctor can find out which treatment you are receiving if required for special situations.

If you are eligible and willing to participate in the study, a consent form must be signed prior to any surveys or treatments being performed. You will be asked a few general questions about your age, medical history, use of pain killer medications, use of laxatives, and your typical bowel habits.

You will then be assigned to one of two groups. Random chance (like the flip of a coin) will determine which group you will be allocated to. You will have a one in two chance of receiving the active treatment medication.

You will proceed with your surgery as planned. Participation in this project will not change your surgical plan, or your hospital care or stay in any way. After your surgery, the surgeons involved with complete a survey about your surgical procedure and the findings, and any pain killer medication prescribed during your hospital stay.

If you are allocated to the control group, you will receive the placebo medication.

If you are allocated to the treatment group, you will receive the active treatment medication.

As mentioned above, neither you or the doctor will know which treatment you receive. The placebo medication is made of a nutritional supplement commonly given to the elderly and newborn babies. It is also

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freely available over-the-counter and does not contain any wheat, gluten, eggs,nuts or Kosher forbidden ingredients and is Halal certified. The active treatment medication is the laxative described above, with the active ingredient Polyethylene Glycol.

Both groups will receive pre-packaged doses of medication which look identical and come in a powder form. The medication is unflavoured and to be mixed with 250mls of any liquid of your choice (ie water, milk, juice, soup). You will be instructed to have one dose of the medication each day for 7 days after your surgery (starting from the evening of surgery). You will be provided with further detailed information on possible side effects to monitor and safety advice. You are free to stop the treatment at any stage if you wish to withdraw from the study or at your choosing if you experience any side effects.

You will receive a survey at 1 week and 6 weeks after your surgery asking about your bowel habits, any side effects experience, your level of pain after surgery, your use of painkiller medication and extra laxatives used. All surveys will be via email link. The survey at the beginning of the study, and at 1 week and 6 weeks after surgery will each take 5-10 minutes to complete.

Participation in the study should not restrict any other usual activities. We recommend you continue your usual diet, your usual medications and usual activities as recommended by your doctors after surgery.

4. What are the possible benefits of taking part?

We can’t guarantee that you will receive any benefits from this project. The potential benefits for those in the treatment group receiving the active medication are a reduced risk of constipation after surgery, which may reduce pain and bother. The treatment medication is a commonly used medication often prescribed by clinicians that does not stray from usual routine medical care.

5. What are the possible risks and disadvantages of taking part?

It is possible for medical treatments to 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 and are worried about them, please speak to your surgeon, or family doctor. As part of the surveys you will be completing in the study (as described above in Section 3), you will be asked about any possible side effects. The results of these surveys will be regularly monitored by the research team. The research team will also check your medical history to make sure that you are not at an increased risk of side effects.

The potential side effects from the medication are usually mild and temporary and include abdominal bloating, cramps or diarrhoea. Severe side effects such as severe diarrhoea leading to hospitalization are rare. You will be given explicit safety information with clear instructions on when to stop the study drug, and when to seek medical attention. You will also be given information on when to take extra laxatives or seek medical attention for constipation. There will be a contact phone number and email available.

**6. What if I withdraw the participant from this research project?**

If you decide to withdraw 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.

7. Participation is Voluntary

Participation in any research project is voluntary. If you do not wish to take part you are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

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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 the Royal Women’s Hospital.

Before you make your decision, a member of the research team will be available to answer any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

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

8. Privacy, Confidentiality and Disclosure of Information

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. You will be allocated a study number and your information will be de-identified. If you give us your permission by signing the Consent Form, we hope to publish the results in a journal or present them at a conference. In any publication, information will be provided in such a way that you cannot be identified.

Information about you may be obtained from your health records held at this health service for the purpose of this research. By signing the consent form you agree to the research team accessing health records if they are relevant to your participation in this research project.

The study data from this research will be written information that will be stored in a locked office and computerised information will be kept in a database that is password protected. Only the research staff involved in this project will have access to this information. All information, which may identify you, will be stored securely for 15 years. After this time all identifying documents and computer files will be destroyed.

In accordance with the Australian Privacy laws, you can request to have access to information collected and held about you during the study, including your medical records. Please contact one of the researchers if you would like to access your information.

9. New Information Arising During the Project

During the research project, new information about the risks and benefits of the project may become known to the researchers. If this occurs, you will be told about this new information. This new information may mean that you can no longer participate in this research. If this occurs, the person(s) supervising the research will stop your participation. In all cases, you will be offered all available care to suit your needs and medical condition.

10. Results of Project

At the end of the study, a summary report of the findings will be made available to all participants. The results may also be used for publication in a medical journal or for presentation at a medical conference.

11. Ethical Guidelines

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 the Royal Women’s Hospital.

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.

12. Further Information or Any Problems

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 their involvement in the project (for example, any side effects), you can contact the principal study doctor as below:

Name: Dr Avelyn Wong

Position: Principal study doctor and principal researcher

Telephone: 8345 2000

Email: womenshealthresearch@thewomens.org.au

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about your rights as a research participant, then you may contact the Royal Women’s Hospital Consumer Advocate on (03) 8345 2290.

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**Consent Form –** *Adult providing own consent*

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**Site:** Royal Women’s Hospital, Parkville

**Consent agreement**

I have read the Participant Information Sheet. 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 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 future health care.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information The Royal Women’s Hospital concerning my disease and treatment for the purposes of this project. I understand that such information will remain confidential.

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

I do not have any of the following:

* Inflammatory bowel disease, bowel cancer, previous bowel resection
* Chronic kidney disease
* Type 1 or Type 2 Diabetes Mellitus
* Allergy to previous laxatives, to Maltodextrin or polyethylene glycol 3350
* Galactosemia

I would like a copy of the result in plain English at the completion of the study.

**Declaration by Participant**

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 participant has understood that explanation.

Name of doctor/researcher (please print).

Signature Date

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

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**Site:** Royal Women’s Hospital, Parkville

**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 the Royal Women’s Hospital.

Name of participant (please print).

Signature Date

In the event that the participants decision to withdraw is communication verbally, the Study Doctor / Senior Researcher should provide a description of circumstances below where possible:

**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 doctor/researcher (please print).

Signature Date