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**Participant Information Sheet and Consent Form**

**Clinical Research**

**Effect of the first laparoscopy in an adolescent and young adult female population and its association with chronic pelvic pain**

**Invitation**

You are invited to participate in a research study into the effect of keyhole surgery (laparoscopy) in an adolescent and young adult population.

The study is being conducted by:

Dr Rebecca Deans (O&G Consultant, Royal Hospital for Women & Senior Lecturer, University of New South Wales)

Dr Jason Chow (O&G Consultant, Royal Hospital for Women)

Dr Jinny Foo (O&G Fellow, Royal Hospital for Women)

Dr Kavita Ravendran (Resident, Prince of Wales Hospital)

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. **What is the purpose of this study?**

The purpose of this study is to investigate whether having key-hole surgery improves pain in the long term, and whether it leads to more surgeries for chronic pelvic pain.

There are many ways to manage pelvic pain, and surgery is just one of them. Currently, there is not enough evidence to confirm that surgery is the gold standard for those with pelvic pain. While surgery can provide information about the cause of pain and help treat the pain, it carries risks and can also make the pain worse. Therefore, there is concern that having surgery too early may not be of benefit. This study hopes to find out if surgery in the adolescent and young adult population is better than the non-surgical treatments such as hormonal tablets and painkillers.

1. **Why have I been invited to participate in this study?**

You have been invited to participate in this study because you are between the ages of 16 and 25, and have pelvic pain. You will not be eligible if you have cancer, do not speak English, are pregnant or are unable to follow up for the next 2 years.

1. **What if I don’t want to take part in this study, or if I want to withdraw later?**

Participation in this study is completely voluntary. If you join the study you can withdraw at any time without having to give a reason. If you decide not to join, it will not affect your treatment in any way. If you agree to join in this study, you will be asked to sign the Consent Form.

1. **What does this study involve?**

Randomised trials are performed as sometimes doctors do not know the best way of treating patients with a particular condition so it is a way of comparing different treatment options. To do this, study participants are put into groups, assigned different treatments and the results are compared to see whether one treatment is better than the other. To make sure the groups are similar, a computer allocates each study participant into a group randomly, like the flip of a coin. Neither the doctor nor the study participant can decide which treatment the participant receives.

The study will be conducted over the next 3 years with a follow up at 6 weeks, 6 months, 1 year and 2 years. If you join you will be randomised to either a surgical arm or non-surgical arm. If you are assigned to surgery, you will be placed on the hospital waiting list for keyhole surgery at the Royal Hospital for Women. If you are in the non-surgical group, you will be managed with pain relief medications, hormonal medications and other medications that have proven benefit for helping pelvic pain.

If you are allocated into one particular group, it does not mean that you cannot move into the other group if you continue to have pain or worsening symptoms. For example, if surgery is required for something seen on investigations, such as ultrasound, then surgery will be booked for you regardless of which group you have been placed into. Similarly, if you are allocated to the surgical group, you will not be denied medical management if you needed it.

All participants will also be asked to fill in a questionnaire with one of our research assistants at 6 weeks after surgery or after starting medications, 6 months, 1 year and 2 years later. This is regardless of which group you are in or whether you changed groups during your treatment. The 6 week follow up will be conducted face to face, while the 6 month, 1 year and 2 year follow up will be conducted via phone call. This will take about 1 hour for each follow up and involve questions about your symptoms, mental health, relationship satisfaction and sexual function.

1. **How is this study being paid for**

The laparoscopy will be part of Medicare in the public hospital as this is considered standard care in the management of pelvic pain. A grant has been awarded to subsidise the running of the study.

1. **Are there risks to me in taking part in this study?**

All medical procedures involve some risk of injury. However, there is no additional risk to participants when compared to routine management of patients with chronic pelvic pain, as we are not providing an alternative treatment to what is already offered.

As part of the management of pelvic pain we often use a number of medications, regardless of whether you have surgery or not.

These medications and their side effects are listed below:

* Contraceptive pill – weight gain, mood swings, abnormal vaginal bleeding, clots blocking the blood supply to the lungs
* GnRH analogues – hot flushes, urinary tract infections
* Analgesics (pain relief medication) – drowsiness, nausea
* Anti-depressants (used as pain relief medication) – dry mouth, constipation
* Non-steroidal anti-inflammatories (like “Nurofen”) – stomach ulcers, kidney impairment

These treatments are used for pelvic pain, and are not different in any way to a patient managed who doesn’t enroll in our study. It is important to note that the majority of these side effects are rare and these side effects may only be an issue in very high doses. Your doctor will tailor your medication according to any side effects or contraindications you may have to any particular medication. It is advised that you contact us, your local doctor or emergency should you develop a severe reaction to any of the medication.

The risks associated with key-hole surgery include:

* Minor complications (3% risk) – nausea, vomiting, shoulder tip pain
* Major complications (0.24% risk) – bowel rupture. This may require a further surgical procedure called a laparotomy
* Anaesthetic risks – nausea, vomiting, skin bruising

The questionnaires to be completed may involve sensitive questions, which can lead to emotional distress or discomfort. If this is the case, you do not have to complete that part of the questionnaire. You will be referred to a social worker or counsellor at any stage of the study if need be.

1. **What are the alternatives to participation?**

You do not have to participate in this research project to receive treatment at this hospital. Despite the group that you are allocated to, the treating clinician will continue to provide standard care for you. If you have been allocated to the non-surgical group and your pain has not improved over time your clinician will determine if surgery will be beneficial in your case. As such, you will not be denied treatment that your clinician deems necessary.

1. **What happens if I suffer injury or complications as a result of the study?**

If you suffer any injuries or complications are a result of this study, you should contact the study doctor as soon as possible who will assist you in arranging appropriate medical treatment.

You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury is caused by negligence of any of the parties involved in the study. If you receive compensation that includes an amount for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital

1. **Will I benefit from the study?**

This study aims to further medical knowledge and it is hoped the findings will improve initial management of pelvic pain in young women. You will have the benefit of being followed up and should there be any concern during the follow-ups, urgent referrals will be made to ensure that your concerns will be addressed as soon as possible. You will also be provided with a gift voucher valued at $20 at the 6-month follow-up and $50 at the 2-year follow-up to thank you for your participation in the study.

1. **Will taking part in this study cost me anything and will I be paid?**

Participation in this study will not cost you anything.

1. **How will my confidentiality be protected?**

Of the people treating you, only Dr Rebecca Deans, Dr Jason Chow, Dr Jinny Foo, Dr Kavita Ravendran will know whether or not you are participating in this study. Any information that is collected about you in connection with this study will be completely confidential, with no names attached to the information. Results will be held securely at Royal Hospital for Women in a secured office.

1. **What happens with the results?**

We plan to discuss and publish the results in medical conferences and journals. In any publication, the information will not be linked in only way to your name or address, so that you cannot be identified. Results of the study can be given to you if you wish.

1. **What happens to my treatment when the study is finished?**

Ongoing treatment of your condition will continue in the future whether you have joined the study or not.

1. **What should I do if I want to discuss this study further before I decide?**

When you have read this information, the researcher, Dr. Jinny Foo or Dr. Kavita Ravendran will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact her on 9382 6111.

1. **Who should I contact if I have concerns about the conduct of this study?**

This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants. You should contact them on 02 9382 3587 or email SESLHD-RSO@health.nsw.gov.au and quote HREC 16/374. Alternatively, you can contact the researchers Dr. Rebecca Deans and Dr. Jinny Foo on 9382 6111 to discuss options and assistance.

Thank you for taking the time to consider this study

If you wish to take part in it, please sign the attached consent form.

This information sheet is for you to keep.



**CONSENT FORM**

 1. I ,.......................................................................................................,
agree to participate in the study described in the participant information statement attached to this form.

 2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

 3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

 4. I understand that participation in this study involves follow-up questionnaires at 6 weeks, 6 months, 1 year and 2 years from the time of randomization.

 5. I understand that I can withdraw from the study at any time without prejudice to my relationship to the Royal Hospital for Women.

 6. I agree that research data gathered from the results of the study may be published and used in future research, provided that I cannot be identified.

 7. I understand that if I have any questions relating to my participation in this research, I may contact Dr Jinny Foo or Dr Kavita Ravendran on telephone, who will be happy to answer them.

 8. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

 9. I understand that 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

 Complaints may be directed to the Research Ethics Secretariat, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031, Australia (Phone: (02) 9382 3587, Fax: (02) 9382 2813, email: SESLHD-RSO@health.nsw.gov.au



**Signature of Participant Please Print Name Date**

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**Signature of Witness Please Print Name Date**

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**Signature of Investigator Please Print Name Date**

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