PARTICIPANT INFORMATION AND CONSENT FORM (PICF)

Participant Information and Consent Form
Mercy Hospital for Women

Vaginal Diazepam following Mirena IUD Insertion

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Associate Researchers: Dr Lauren Hicks
Dr Lenore Ellett

1. Introduction

You are invited to take part in this research project. This is because you have been booked to have a Mirena IUD inserted in the outpatient clinic. This research project is trying to determine whether giving a single dose of diazepam (a muscle relaxant) reduces the cramping experienced by patients after having an IUD inserted.

This Participant Information and Consent Form tells you about the research project. It explains the procedures 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 to take part, you might want to talk about it with a relative, friend or healthcare worker.

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

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 take part in the research project;
- consent to participate in the research processes 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 project?

Many women experience mild-moderate cramping in the days following insertion of their IUD. Many treatments for this have been studied, and the most helpful treatment is anti-inflammatory medications (such as ibuprofen). We are studying whether a medication called diazepam (sometimes referred to by the trade name Valium) administered in the vagina, can act as a muscle relaxant to reduce uterine cramping after IUD insertion. In this study diazepam will be compared to a placebo ('dummy' treatment).

3. What does participation in this research project involve?

If you agree to participate in the research project, you will be required to complete a questionnaire detailing your past medical, obstetric and gynaecological history and well as the reasons for having an IUD inserted.

Before you have your IUD inserted you will be randomly allocated to receive either diazepam (10mg vaginal pessary) or a placebo (a pessary identical in appearance but not containing any medication).

Following the insertion, a pessary will be placed in your vagina. Neither you nor the doctors treating you will know if you have received the diazepam ('active') pessary or the placebo.

You will be asked to complete a questionnaire about your experience of the IUD insertion prior to leaving the hospital.

You will require a support-person to drive you home from the hospital or accompany you on public transport.

You will be emailed a follow-up questionnaire 24 hours, 3 days and 7 days after insertion for you to report on the cramping you experience and any adverse reactions to the treatment.

You will attend your routine 3-month follow-up appointment to check on the IUD placement.

Participation in this research project does not require you to make additional visits to the hospital other than those routinely required for patients following IUD insertion. You will not be paid for participation in the research.

4. What are the possible benefits?

You have a 50% chance of receiving the active medicine (diazepam). There may be a reduction in the cramping you experience following the IUD insertion, however there may be no difference.

5. What are the possible risks?

The possible risks include:

Serious risks:

- Allergy to the medication or components

Minor risks:

- Drowsiness

- Fatigue

- Muscle weakness

- Headache

These are uncommon risks affecting less than 20% of women using this medication in other settings.

If you experience drowsiness, you must not operate a motor vehicle until the symptom has resolved.

6. What if new information arises during this research project?

During the research project, new information about the use of vaginal diazepam may become available to researchers. If this occurs, you will be told about this new information and the researcher will discuss whether this new information affects you.

7. Can I have other treatments during this research project?

It is important to tell your doctor and the research 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 doctor about any changes to these during your participation in the research.

8. Do I have to take part in this research project?

Participation in any research project is voluntary. You do not have to participate. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. Your decision whether or not to take part in the project will not affect your management or timing of IUD insertion.

9. What if I withdraw from this research project?

If you decide to withdraw, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to ensure you are safely withdrawn, and are not inconvenienced by the process.

If you choose to withdraw, you may be asked your reasons for doing so, so to better understand any issues with our research design. Any collected clinical data pre-dating your withdrawal will be retained confidentially, as described (see section 12). However, your data will not be included in the final analysis, and no further information will be sought following your withdrawal.

10. How will I be informed of the results of this research project?

The results of the research project will be published in a peer-reviewed journal. A summary of the results will be made available by an email or letter to the participants.

11. What else do I need to know?

Please don't hesitate to ask a member of the research team if you have any questions that are not answered by this booklet. See below for contact details.

12. What will happen to information about me?

Any information collected about you will be de-indentified and stored electronically on a password protected research database. Only the researchers will have access to the information collected for the study. All of the data collected for the study will be securely destroyed after 7 years.

In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

13. How can I access my information?

In accordance with relevant Australian and/or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

14. Is this research project approved?

The ethical aspects of this research project have been approved by the Human Research Ethics Committee (HREC) of the Mercy Hospital for Women.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research* (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

In accordance with the National Medical Health and Research Council guidelines, the HREC is required to conduct audits of research projects from time to time. It may therefore be possible that the HREC, which has approved this research, will seek to view a copy of your signed consent form, or to contact you, to ensure that the research is being conducted according to the ethical standards of these guidelines.

15. Consent

I have read, or have had read to me in a language that I understand, this document and I understand the purposes, procedures and risks of this research project as described within it.

I give permission for the administration of a vaginal pessary containing either diazepam or placebo to be administered following my IUD insertion.

I give permission to be contacted by email to complete follow-up questionnaires.

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

I freely agree to participate in this research project as described.

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

Participant's name (printed) ……

Signature Date

Name of witness to participant's signature (printed) ……

Signature Date

Declaration by 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.

Researcher's name (printed) ……

Signature Date

I consent to the Mercy Health Human Research Ethics Committee which has approved this study to access my information, or to contact me to ask about my research experience, in order to ensure that the project is being run in accordance with government standards:

Yes □ No □

I consent to being approached for future research projects related to my IUD insertion:

Yes □ No □

** A senior member of the research team must provide the explanation and provision of information concerning the research project.*

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

16. Who can I contact?

For further information regarding the project:

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project, please contact:

a) The lead researcher, Dr Lauren Hicks, on 03 8458 4802

b) The principal researcher on 03 8458 4444 (via main hospital switchboard)

For further information regarding your gynaecology appointment:

If you have questions or concerns regarding your outpatient clinic appointment(s), please contact the outpatients department

For complaints:

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:

Name:

Revocation of Consent Form

Full Project Title: Vaginal Diazepam following Mirena IUD Insertion

I hereby wish to WITHDRAW my consent to participate in the research proposal named above and understand that such withdrawal WILL NOT affect any treatment or my relationship with Mercy Hospital for Women.

Participant's Name (printed) …….

Signature Date

Please return form to:
Dr Lauren Hicks
Mercy Hospital for Women
163 Studley Rd
Heidelberg 3084