**PARTICIPANT INFORMATION SHEET AND INFORMED CONSENT FORM**

1.   **Title of study**:  COMPARISON BETWEEN THE EFFECT OF DIENOGEST AND SHORT TERM GnRH ANALOG IN ENDOMETRIOSIS PRIOR TO LAPAROSCOPIC CYSTECTOMY: A PROSPECTIVE STUDY

2.   **Name of investigator and institution:** Dr.Aizura Syafinaz bt Ahmad Adlanand Dr Shrilekha Suriya Narayanan of Department of Obstetrics & Gynaecology, UMMC

**3.**      **Introduction:**

You are invited to participate in a research study because you have been diagnosed with endometriosis and planned for a laparoscopic cystectomy. The details of the research trial are described in this document. It is important that you understand why the research is being done and what it will involve. Please take your time to read through and consider this information carefully before you decide if you are willing to participate. Ask the study staff if anything is unclear or if you like more information. After you are properly satisfied that you understand this study, and that you wish to participate, you must sign this informed consent form. To participate in this study, you may be required to provide your doctor with information on your health history; you may harm yourself if you are not truthful with the information provided.

Your participation in this study is **voluntary**. You do not have to be in this study if you do not want to. You may also refuse to answer any questions you do not want to answer.  If you volunteer to be in this study, you may withdraw from it at any time. If you withdraw, any data collected from you up to your withdrawal will still be used for the study. Your refusal to participate or withdrawal will not affect any medical or health benefits to which you are otherwise entitled.

This study has been approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia. NMRR ID:  NMRR-16-317-29736. MECID No.: 20159-1645

**5.**      **What is the purpose of the study?**

The purpose of this study is to see the effectiveness of this treatment prior to the operation and how it will affect the outcome of the operation for the treatment of endometriosis. This research is necessary because it will help in the treatment of endometriosis to review whether or not pre-treatment hormonal therapy will facilitate in better /easier peeling of the cyst wall as well as to evaluate the treatment effect towards remaining ovarian reserve.

Till today, there is not much information or study done on preoperative hormonal preparation of the cyst. Hypothetically the use of these hormones will cause easier extraction of the cyst wall making the surgery easier and hypothetically will reduce the blood loss intraoperatively. Reduced blood loss and easier surgery will ultimately result in better surgical outcome and better postoperative recovery for patients.

A total of 60 subjects like you will be participating in this study; in Malaysia, The whole study will last about 1 year and your participation will be for about 1 year.

**6.**      **What kind of study products/ procedure will I receive?**

If you agree to participate in the study, the doctor may need to perform some tests and examinations to determine if you are suitable for the study. If you are deemed suitable, you will be randomly (by chance, like flipping a coin) assigned to one of the treatment groups below. You have equal chance of being assigned to each of the groups.

The study products do not contain porcine, bovine or animal components

Group 1: No pretreatment administered pre-operatively (control group)

Group 2: single dose of GnRH analogue will be given (s/c lucrin 3.75mg) 1 month prior to the surgery date

Group 3: oral dienogest 2mg daily will be given to be taken for 30 days

all patient will undergo laparoscopic cystectomy after 1 month duration of treatment

**7.**      **What will happen if I decide to take part?**

*a)*  *prior to the initiation of the study, blood will be taken for series of investigation- for AMH, Ca 125, FSH/LH level, transvaginal ultrasound will be performed to look for antral follicular count*

*b)*   *you will be given medication as what has been assigned*

*c)*   *a laparoscopic cystectomy will be performed  1 month after the initiation of treatment*

*d)*  after the operation you will also be assessed regarding overall satisfaction of the treatment that you have received

**8.**      **When will I receive the trial product and how should it be kept?**

You will be given the study product at each study visit throughout the treatment period of the study. You must not give the product to anyone else. The study staff will instruct you on how the product must be handled and stored. Please ensure that you keep your used and partly used study products after you have finished with them. For some visits you will need to bring back all study products (partly used, unused and empty packaging material) to your study site.

**9.**      **What are my responsibilities when taking part in this study?**

It is important that you answer all of the questions asked by the study staff honestly and completely. If your condition or circumstances change during the study, you must tell the study doctor. There may be certain medications that you cannot take while participating in this study. The doctor will discuss those medications with you. You must not take any other medications without consulting your study doctor. You must inform your study doctor immediately if you make any changes to any of your current treatments, even those which you have been taking for a long time.

It is very important that your study doctor be informed very rapidly of any eventual changes to your health during your participation in the study. For your own security, it is important that you follow your study doctor’s instructions throughout the entire duration of the study.

**10.**  **What kind of treatment will I receive after my participation in the trial?**

No study product will be given to you at the end of your participation in the study. Whether you complete the study or withdraw early, your doctor will discuss the best alternatives for your future treatment with you.

**11.**  **What are the potential risks and side effects of being in this study?**

You may experience nausea, vomiting, breast engorgement, irregular menstrual bleed, abdominal cramps, flatulence, sleep disorder, loss of libido, altered mood, migraine, however the side effect is less common in short term therapy

Please ask your study doctor if you need more information on risks and side effects. The trial staff will inform you in a timely manner about any new findings or changes about the study product which may affect your health or willingness to continue in this study. Where necessary, you may be asked to re-consent to participate.

**12.**  **What are the benefits of being in this study?**

There may or may not be any benefits to you. Information obtained from this study will help improve the treatment or management of other patients with the same disease or condition.

**13.**  **What if I am injured during this study?**

If you are injured as a result of being in this study, you should contact your study doctor. Care and management of a bodily injury or illness will be as per standard management protocol. The sponsor is not responsible for medical expenses due to pre-existing medical conditions, any underlying diseases, any ongoing treatment process, your negligence or willful misconduct, the negligence or willful misconduct of your study doctor or the study site or any third parties. You do not lose any of your legal rights to seek compensation by signing this form.

**14.**  **What are my alternatives if I do not participate in this study?**

You do not have to participate in this study to get treatment for your disease or condition. There are still alternative treatments which are available. The study doctor will discuss in more details the benefits and risks of those treatments with you.

**15.**  **Can the research or my participation be terminated early?**

The study doctor or the sponsor may due to concerns for your safety, stop the study or your participation at any time. If the study is stopped early for any reason you will be informed and arrangements made for your future care. You may be asked to attend a final follow-up visit.

**16.**  **Will my medical information be kept private?**

All your information obtained in this study will be kept and handled in a confidential manner, in accordance with applicable laws and/or regulations. When publishing or presenting the study results, your identity will not be revealed without your expressed consent. Individuals involved in this study and in your medical care, qualified monitors and auditors, the sponsor or its affiliates and governmental or regulatory authorities may inspect and copy your medical records, where appropriate and necessary.

Data from the study will be archived and may be transmitted outside the country for the purpose of analysis, but your identity will not be revealed at any time.

**18.**  **Who should I call if I have questions?**

If you have any questions about the study or if you think you have a study related injury and you want information about treatment, please contact the study doctor, Dr Shrilekha Suriya Narayanan (*0123467207)* and Dr. Aizura Syafinaz bt Ahmad Adlan *(012-3375808)*

If you have any questions about your rights as a participant in this study, please contact: The Secretary, Medical Research & Ethics Committee, Ministry of Health Malaysia, at telephone number 03-2287 4032.

**INFORMED CONSENT FORM**

Title of Study: COMPARISON BETWEEN THE IMPACT OF DIENOGEST AND SHORT TERM GnRH ANALOG IN ENDOMETRIOSIS PRIOR TO LAPAROSCOPIC CYSTECTOMY: A PROSPECTIVE STUDY

By signing below I confirm the following:

·         I have been given oral and written information for the above study and have read and understood the information given.

·     I have had sufficient time to consider participation in the study and have had the opportunity to ask questions and all my questions have been answered satisfactorily.

·         I understand that my participation is voluntary and I can at any time free withdraw from the study without giving a reason and this will in no way affect my future treatment. I am not taking part in any other research study at this time. I understand the risks and benefits, and I freely give my informed consent to participate under the conditions stated. I understand that I must follow the study doctor’s (investigator’s) instructions related to my participation in the study.

·        I understand that study staff, qualified monitors and auditors, the sponsor or its affiliates, and governmental or regulatory authorities, have direct access to my medical record in order to make sure that the study is conducted correctly and the data are recorded correctly. All personal details will be treated as STRICTLY CONFIDENTIAL

·         I will receive a copy of this subject information/informed consent form signed and dated to bring home.

·         I agree/disagree\* for my family doctor to be informed of my participation in this study. *(\*delete which is not applicable)*

**Subject:**

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |   | I/C number: |  |
| Name: |  | Date: |  |

**Investigator conducting informed consent:**

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |  | I/C number: |  |
| Name: |  | Date: |  |

**Impartial witness:** *(Required if subject is illiterate and contents of patient information sheet is orally communicated to subject)*

|  |  |  |  |
| --- | --- | --- | --- |
| Signature: |  | I/C number: |  |
| Name: |  | Date: |  |