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Evaluation of Using Dienogest and N-Acetyl Cysteine on the Volume of Uterine Leiomyoma

Faculty of Medicine
Ain Shams University
2023- 2024

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Ethical Committee of Scientific research

Informed consent form for patients who are invited to participate in the research

Research title: Evaluation of Using Dienogest and N-Acetyl Cysteine on the Volume of Uterine Leiomyoma

Introduction and aim of the work:

Leiomyoma is a relatively common benign tumor. It is the most common cause of abnormal uterine bleeding and pelvic pain .Leiomyoma originates from the smooth muscle of the uterus and its incidence is 4.5%–68.6%. there are numerous clinical presentations, for instance, pressure on adjacent organs, infertility, abnormal uterine bleeding, and obstetric complications .Leiomyoma is considered the most common cause of gynecologic surgery worldwide

The aim of the present study is to assess the effect of Dienogest and NAC on the volume of uterine leiomyoma in women previously diagnosed with leiomyoma.

Place of work:

The study will be conducted at Ain Shams University Maternity Hospital (ASUMH) “outpatient gynaecology clinic”

Number and Selection of participants:

Will be 40 participants,

- Group (A): women will receive Dienogest, with brand name GYNOPROGEST, 2mg pills daily for 3 months (20 cases)
- Group (B): women will receive NAC, with brand name GEMACYSTEINE, orally at a dose of 600 mg/day for 3 months (20 cases)

Plan of the work:

After your consent achievement and fully explained about the steps of research, the subjects of both groups will be subjected to the following:

Clinical parameter

- Full history taking: with special emphasis to age, parity, BMI, age of menarche, obstetric history, drug history as well as presence of any medical disease.
- Full general examination: for pallor, fatigue.
- Abdominal examination: to assess the leiomyoma size, surface, contour and consistency.
- Bimanual vaginal examination(for uterus <12 weeks): to confirm its uterine origin.

Laboratory parameters:

1. CBC. To assess Hb level.

Radiological parameters:

- Vaginal Ultrasound examination with the addition of a transabdominal approach if needed to diagnose and assess the leiomyoma (size and number)before and after 3 months.
- Ultrasound will be done by the same radiologist using the same machine.

Benefits expected from the study:

Benefits to the participants:

Decrease the surgical insult by apply new medication of less cost ,high efficacy,less side effects,more potent in reducing the tumor size.

Benefits to the community:

Decrease overall morbidity & mortality of that tumor of high distribution in the community.

Conducting the consent:

The consent will be conducted to the patient by the investigator, Doctor Esraa Mosaad Awd in the obstetrics and gynecology Department, Ain Shams University Hospital. Literate individuals will be left to read the consent followed by its explanation by the mentioned investigator, while illiterate individuals will have the consent read and explained to them as well.

Risks and complications:

This research will not expose your patient to further risks or complications despite the standard risks of protocol of Ain Shams University hospitals.

- ***The risk of NAC side effects:*** stomatitis, nausea, vomiting, fever, rhinorrhea, drowsiness, fatigue, chest tightness, and bronchoconstriction

***As for Dienogest*:** Headache, Back pain,Breast tenderness,Hot flushes,Mood changes,Acne,Stomach discomfort (e.g. nausea, vomiting, abdominal pain and Weight gain.

- ***Abdominal Ultrasonopgraphy:*** is a non-invasive, rapid bedside method to assess status of the uterus. This device uses ultrasound waves. These waves carry no recognized risks or side effects and are not known to cause or aggravate any medical condition.

Alternatives to participating:

In case of refusing to participate in this research, your patient will be followed up and will receive his treatment as planned.

Confidentiality:

You will deal in complete confidentiality, and no one has right to read your patient medical information except the main researcher. After the research is complete, you will be informed regarding your patient `s research results and also further information regarding your patient `s health status.

Right to refuse or withdraw:

Any participant doesn`t have to take part in this research if he/she or want. They may also stop participating at anytime. If you have read this form and have decided to let your patient to participate in this study, please understand that your patient's participation is voluntary and you have the right to withdraw your consent or discontinue participation at any time without penalty or loss of benefits to which your patient is otherwise entitled. Your decision whether or not to participate in this study will not affect your patient's medical care. Individual privacy will be maintained in all published and written data resulting from the study.

Contact Information:

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and

benefits, or alternative courses of treatment, you should ask the investigator, Esraa Mosaad Awd at mobile number: 01019000586. You can also call the assistant supervisor Dr. Amr Saad Mahmud at mobile number: 01010051381. If you have any problems or concerns about the study, you can also call Prof. Ahmed Mohamed Rateb the main supervisor at mobile phone number: 01123600576

You do not have to sign this consent form. But if you do not, your patient will not be able to participate in this research study.

Certificate of consent:

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I ask have been answered to my satisfaction. I consent voluntary to participate in this research and understand that I have the right to withdraw from the research at any time without in any way affecting my patient`s medical care.

- Name of participant:
- Signature:
- Identity number or finger print: …….
- Date:

I have accurately read or witnessed the accurate reading of the consent to the potential participant. The individual has had the opportunity to ask questions I confirm that the individual has given consent freely.

- Name of researcher:Esraa Mosaad Awd.
- Signature of researcher:
- Date:

This proposal has been reviewed and approved by Ethical Committee of Scientific research, which is a committee whose task is to make sure that research participants are protected from harm.

On .....

This consent is valid until .....

Chairman of the Committee: Committee Seal: