Depth of Necrosis in Normal Cervical Epithelium After 85% Trichloroacetic Acid (TCA) Application

EXPLANATION FORM FOR STUDY SUBJECT CANDIDATES

- Principal Investigator: Laila Nuranna
  Professor of Oncology Gynecology
  Indonesian University and Cipto Mangungkusumo Central Hospital

- ClinicalTrials.gov identifier : NCT04911075
- Unique Protocol ID : 21020134
- Version Date : 15/02/2021

ETHICS COMMITTEE FOR HEALTH STUDY FKUI-RSCM
EXPLANATION FORM FOR STUDY SUBJECT CANDIDATES

I am a part of the Research Team supervised by Laila Nuranna, Professor from the **Department of Gynecology Oncology FKUI-RSCM.** We will conduct a research titled **Depth of Necrosis in Normal Cervical Epithelium After 85% Trichloroacetic Acid (TCA) Application**.

We would like to inform you about this study and invite you to take part in this study.

You can participate in this study by signing this form. You have the right to withdraw from the study at any time. You have the right to receive new information from us about the treatments that are being tested. If you refuse to participate in or withdraw from this study, it will not affect your relationship with us and and the standard of care provided by this hospital.

If you do not understand any of the statements in this form, please do not hesitate to ask me.

1. **Study purposes**

   To determine the depth of the cervical epithelial cell death process (necrosis) after application with 85 percent TCA solution. TCA is a chemical solution that has long been used for cosmetics (peels) and to treat skin diseases (genital warts).

2. **Participation in this study**

   If you decide to participate in this study, you will be asked your willingness. This study will involve 40 subjects. In this study, your cervical epithelium will be applied with 85 percent TCA solution. The time of application is 24 hours before total hysterectomy procedure that had been planned for you. Each procedure will take approximately 30 minutes.

3. **The reason choose you as astudy subject**

   The selection of this study subject is based on normal cervical epithelium conditions on the visual inspection of the cervix with acetic acid (VIA) test and would undergo elective total hysterectomy within 24 hours on indication other than cervical pathology.

4. Study procedure

4a. Drug Information or Intervention Procedures

1. The doctor will interview you and ask you questions such as your name, age, medical history, history of using birth control pills, number of children, and method of delivery.
2. Undergo physical examination by a doctor to assess general physical health status and followed by a cervical examination using a vaginal speculum.
3. Perform VIA test by applying 5% acetic acid to the cervix. If the result is negative, then it will continue with 85% TCA application.
4. Application of the 85% TCA solution uses a vaginal speculum protected by a condom. 85% TCA solution will be applied to the entire surface of the cervix and then let stand for 2-3 minutes.
5. After application of 85% TCA solution, you will be monitored for 24 hours in the treatment room, especially regarding complaints of pain and / or signs of allergies.

4b. Procedures or alternative treatments currently available

This study is conducted on subjects with a normal cervix.

5. Risks, side effects, and management

You may experience mild pain complaint, which can be treated with pain-relieving tablets (paracetamol, mefenamic acid). Moreover, allergies may also occur which can be treated by administering anti-allergy tablets (dexamethasone).

6. Benefits

- Subjects can perform a VIA test before surgery to assess the condition of the cervix and for early detection of pre-cancerous lesions.
- Participation in this study will contribute to health sciences and national health programs, especially for cervical cancer prevention programs and the management of pre-cancerous lesions.

7. **Compensation**

In this study, each subject will be compensated with a sum of money equivalent to Rp. 100.000, - (One Hundred Thousand Rupiah).

8. **Financing**

The investigators will cover all study expenses.

9. Confidentiality

- All study data will be kept confidential in the form of digital files stored on a *hard disk* with a secret lock code.
- The investigator team has also signed a Study Data Confidentiality Form with a stamp stating that it will maintain the confidentiality of data and study subjects.
- Your name will not appear in publications or presentations of the study results at scientific meeting or conferences
- The study data will be accessible to ethics committes and national regulatory agencies in order to the study data verification

10. Obligations of study subjects

As a study subject, you should follow the study rules or guidelines as written above. If something is unclear, you can contact the study team for clarification.

11. Right to refuse and withdraw

You do not have to participate in this study if you do not wish to. You must understand that even if you agree to participate, you have the right to withdraw from this study. If you refuse to participate or withdraw from this study, that decision will not affect your relationship with us and will not affect the standard of care in this hospital. I will allow you at the end of this explanation to be able to consider the decisions that you will be taken.

12. Post-study access

After this study ends, you will get access to the study results and will be uploaded to the official FKUI website at the following address: http://study.fk.ui.ac.id

13. Additional information

You are allowed to ask all the things that are not clear about this study. If at any time there are side effects or need further explanation, you can contact Laila Nuranna, Professor or Dolly Nurdin Lubis, Ob/Gyn, Phone Number 08122436967, Doctor in The Department of Gynecology Oncology RSCM / FKUI.

FKUI

RSCM
Rumah Sakit Umum Pusat

Health Study Ethics Committee
FMUI-RSCM

AGREEMENT FORM FOR PARTICIPATION IN THIS STUDY

All these explanations have been informed to me and all my questions have been answered by Laila Nuranna, Professor/ Dolly Nurdin Lubis, Ob/Gyn. I understand that if I need an explanation, I can ask Laila Nuranna, Professor/ Dolly Nurdin Lubis, Ob/Gyn

Certificate of Approval (Consent)	
I have read all the descriptions of this study. I have been allowed to ask questions and all my questions have been answered clearly. I am willing to participate in this study voluntarily. _____ Name of the subject _____ Subject signature Date_____ Date/month/year	I confirm that participants have been allowed to ask questions about this study, and all questions have been answered correctly. I confirm that consent has been given voluntarily. _____ Name of the investigator _____ Investigator signature Date_____ Date/ month / year

Study Information

Principal Investigator : **Laila Nuranna, Professor**

Study team

- **Sigit Purbadi, Ob/Gyn (C)**
- **Andi Darma Putra, Ob/Gyn (C)**
- **Tofan Widya Utami, Ob/Gyn (C)**
- **Wawaimuli Arozal, PhD**
- **Primadewi Kusumadjati., PATH (C)**
- **Aria Kekalih, Dr**
- **Dolly Nurdin Lubis, Ob/Gyn**

Correspondence

- **e-mail : doelhappy@gmail.com**
- **HP : 08122436967**

KEPK FKUI-RSCM: Salemba Street No 6, Central Jakarta, 10430

Phone: 021 3157008

E-mail: ec_fkui@yahoo.com