

RV 306

Information Sheet for Additional Cervical Biopsy Collection for Female Volunteers in the study

Study Title

Randomized, Double Blind Evaluation of Different One-Year Boosts after Sanofi Pasteur Live Recombinant ALVAC-HIV (vCP1521) and Global Solutions for Infectious Diseases (GSID) gp120 B/E (AIDSVAX[®] B/E) Prime-Boost Regimen in HIV-uninfected Thai Adults

Short title: Prime and Multiple Boost HIV Experimental Vaccine Project

We would like you to thoroughly read and understand this document before signing the form.

Attention the Study Participants

Before deciding to participate in cervical biopsy collection, please read this document thoroughly. In doing so, you will acknowledge rationale and details of this sample collection. If you have any further questions, please feel free to ask the study team or investigator doctors or nurses at all times. The investigators will answer and clarify any matter.

You are also able to ask advice about participation in this cervical biopsy collection from your family, friends, or your personal doctor. You have enough time to make a decision freely until the targeted number of volunteers has been enrolled. If you finally decide to participate in this study, please sign the consent form. You will receive a copy of the document.

1. Purpose and Background

HIV can penetrate into the human body through the mucous membranes, especially in genital and anal area. For women, the cervical and vaginal mucous membranes are the main routes for HIV to enter the body during sexual intercourse. It is crucial to understand the local immune responses. Therefore, cervical biopsy is needed to get the tissues to evaluate the immune response of the cell after receiving vaccinations. Results of this study may help the

scientists understand how the immune responses may protect against the virus and use it to develop a better HIV vaccine in the future.

2. Cervical biopsy Process

There are approximately 41 volunteers from four groups of the study. Group 1 volunteers will be collected samples in the 26th week. Groups 2 and 3 will have the cervical biopsy performed in the 50th week. Group 4a will have the cervical biopsy performed at the 62nd week. Group 4b will have the cervical biopsy performed at the 74th week. This procedure will be done at Thai Red Cross AIDS Research Centre.

After you have decided to participate in this procedure, the investigator doctor will also perform a pelvic examination and insert an instrument into the vagina to collect specimen for cervical cancer screening and *Trichomonas vaginalis* tests. Your urine also will be tested for Gonorrhea and Chlamydia.

If any of these tests are abnormal, you will be referred for appropriate treatment.

If you are also participating in the mucosal secretion collections, you will not need to have this pelvic and lab testing mentioned above repeated.

Before performing this procedure, you will be asked you to avoid some drugs such as aspirin and anti-inflammatory drugs (the investigator will explain this to you) for seven days before and one day after the cervical biopsy.

Before and/or after the procedure, up to 10 ml of blood may be drawn to test for safety labs depending on the institutional requirement.

This sample collection may cause irritation or bleeding at cervical area, which increases risk of HIV infection and other sexual transmitted diseases. Therefore, you will be asked to abstain from sexual intercourse for three days before and seven days after the cervical biopsy.

You will be tested for pregnancy to ensure that you are not pregnant prior to the collection process. Then, an obstetrician/ gynecologist will use a vaginal speculum (the same as used in a pelvic examination) and use an instrument to cut 2-3 small pieces of cervical tissue about the size of match head. The biopsy process takes approximately 30 minutes without staying in the hospital. You can go back home if there are no abnormal symptoms. You may have pelvic pain, the same as menstruation pain. This pain can be relieved by taking paracetamol or similar pain reliever medication except aspirin.

The study project will arrange the transportation and accommodation. Also, a staff will accompany you on the way to and back from study site for cervical biopsy. Accommodation will be offered for volunteer's convenience and not for medical need as this procedure is done as outpatient procedure. You do not have to pay anything.

3. Risks of Cervical Biopsy

You may feel uncomfortable or shy about the pelvic examination. In order to reduce that feeling, all procedures will be performed in a closed room and the examination is done by the experienced obstetrician / gynecologist. You may feel discomfort during the pelvic examination and feel pelvic pain during the cervical biopsy. In addition, there might be slight bleeding in cervical biopsy sites which will be stopped by the doctor. This procedure will be performed by an experienced obstetrician / gynecologist in order to minimize these risks.

4. Your Benefits from Cervical Biopsy

You may not directly benefit from the cervical biopsy. However, if there are any abnormalities in your pelvic examination or cervical cancer screening results which are parts of this process, you will be referred to an obstetrician / gynecologist for appropriate treatment and you may not be eligible for the cervical biopsy collection. In addition, this study data will provide the investigators a better insight into the human immune system and will be used for HIV vaccine development in the future.

5. Compensation for Cervical Biopsy Sample Collection

You will be compensated for your time, travel expenses, and missed wages for travelling to the appointment for cervical biopsy in amount of 2,000 Baht (two thousand Baht only).

6. Sample Storage

Cervical biopsy samples will be kept and labeled using a barcode with a numeric code; your personal information is not presented. These samples will be sent for laboratory analyses inside or outside Thailand.

The samples will be frozen and kept at HIV Vaccine Research Center of Excellence, Royal Thai Army Medical Department, Thailand.

If you withdraw from this study, your cervical biopsy sample and information collected until the withdrawal date will be used to study your body's immune response to the vaccines.

7. Future Study

If you are willing, these cervical biopsies will be stored for future use in laboratory tests which are related to this study's objectives. Investigators inside and outside of Thailand may request to study these samples. Other future studies require to use these samples need to ask for approval from the Ethical Committee or Institutional Review Board which oversee the medical study in order to protect rights and welfare of human volunteers.

The investigator team may ask to study genetic characteristics of your biopsy sample under the protocol. Genetic study is conducted to better understand your immune response to vaccine.

Your stores sample for analysis will be used for study purposes use only. They will not be sold or purchased.

Result obtained from the study of your sample may lead to new product development in the future. However, you will not receive any additional compensation.

The study team will ask for your permission to store the cervical biopsy for future use. After study closure, your remaining specimens will be stored for 5 years. If there is a need for it to be kept longer than that, the research team will inform and ask for approval from the responsible organization and the Institutional Review Board/Ethical committees. These committees may approve storage of the sample for more than 5 years if necessary in the future.

You can withdraw your permission to store your tissue sample for future use at anytime by contacting the study staff. If you do not allow storage of this sample, your sample will be destroyed upon completion of the study according to the local guidelines.

8. If you get sick or injured from cervical biopsy collection

If you get sick or injured to cervical biopsy collection, you will receive appropriate medical treatment and care as provided with two types of coverage by a limited fund and a clinical trials medical insurance policy that will be obtained by the study sponsor. While we anticipate the combination of the set-aside fund and the insurance policy is more than enough to pay for the costs associated with this study, there is a limit to the amount of coverage available.

However, you will not get any other compensation. You should ask the Principal Investigator or the Co-Investigators about this matter completely before making a decision to participate in this sample collection. If you have any question about illness or injury related to this sample collection, you can contact the Principal Investigator or designee, 1) Punnee Pitisuttithum, MD, Tel. 08 1829 4906 2) LTG. Sorachai Nitayaphan, Tel 08 1625 1531

9. If you are not willing to participate in cervical biopsy sample collection

You can withdraw from cervical biopsy sample at anytime by informing the staff of your decision. A decision to withdraw will not affect study participation as well as not affect rights for treatment and health you are entitled to.

10. Other options to participate in cervical biopsy sample collection

If you decide not to participate in cervical biopsy sample collection, you may still decide to participate in other sample collections.

11. If you need more information or have additional questions

If you would like to ask how to behave as being the volunteer of this study or if you have any problems or questions regarding the work of study staff, you can ask the Principal Investigator or the following assigned person;

Punnee Pitisuttithum, MD
Vaccine Trial Center
Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Road, Bangkok
Tel: 0 2245 5919

LTG. Sorachai Nitayaphan, MD
The Armed Forces Research Institute of Medical Sciences, Thai party
315/6 Ratchawithi Road, Bangkok
Tel. 08 1625 1531

If you do not receive proper treatment for any injury or illness resulting directly from the study or you are not treated as stated in the information sheet for study participant or if you have any question regarding your rights, you can complain at

Ethics Committee of the Faculty of Tropical Medicine, Mahidol University
c/o Research and Academic Services
4th Floor, The 60th Anniversary of His Majesty the King's Accession to the Throne Building
Faculty of Tropical Medicine, Mahidol University
420/6 Ratchawithi Road, Bangkok 10400, Thailand
Tel: 0 2354 9100-19, ext. 1349

Royal Thai Army Medical Department Institutional Review Board
The 5th floor, Phramongkutklao Medical Building
Phramongkutklao College of Medicine
315 Ratchawithi Road,
Bangkok 10400 Thailand
Tel. 0 2354 7600 ext. 94270; 0 2354 9011

Institutional Review Board,
Faculty of Medicine, Chulalongkorn University
1873 Rama 4 Road, Pathumwan, Bangkok 10330
Tel. 0 2256 4455 ext 14, 15

The Ethical Review Committee of Research in Human Subjects
Ministry of Public Health,
Office of the Secretary, 3rd Floor, Department of Medicine Services Building,
Tiwanon Road, Nonthaburi 11000,
Tel 0 2590 6171-2
Fax 0 2591 8251