

RV 306
Information Sheet for Additional
Sigmoid Biopsy Collection 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 sigmoid biopsy collection, please read this document thoroughly. In doing so, you will acknowledge the rationale and details of this sample collection. If you have any further question, 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 biopsy sample 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

The large intestine is one part of the digestive system which contains a large amount of immune cells. Therefore, to understand the immune response in this area after receiving the vaccination is vital. Result obtained from this study may help the scientists to develop a better HIV vaccine in the future.

Sigmoid biopsy collection is performed to get the tissue to evaluate the immune cell

responses of the large intestine after receiving vaccinations.

2. Sigmoid Biopsy Process

The study needs approximately 41 volunteers to participate in the sigmoid biopsy process from four groups. If you are in Group 1, the procedure will be performed in the 26th week. Groups 2 and 3 will have the sigmoid biopsy performed in the 50th week. Group 4a will have the sigmoid biopsy performed at the 62nd week. Group 4b will have the sigmoid biopsy performed at the 74th week. An additional 30 cc (2 table spoons) blood will be collected at one or two weeks prior the sigmoid biopsy. This will allow us to compare immune response between your blood and sigmoid.

After you have decided to participate in this procedure, the doctor will examine your anus. Also you will be tested for Gonorrhea and Chlamydia. (Normally by urine test but rectal swab test will be done if you practices receptive anal intercourse in the past 6 months.)

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 exam and lab testing mentioned above repeated.

Biopsy samples will be collected from the sigmoid using an endoscope with a tiny camera and light at the end. This method is generally used for large intestine cancer screening for person age over 50 years or anyone younger with family history of large intestine cancer. This sample collection will be performed by a gastroenterologist at Chulalongkorn Hospital.

Before performing this procedure, the investigator would like to ask you to avoid certain drugs such as aspirin and anti-inflammatory drugs (the investigator will explain this to you) for seven days before and one day after the biopsy. As a precaution measure, please refrain from having anal sexual intercourse three days before and seven days after this sigmoid 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.

For female participants, you will be tested for pregnancy before the procedure to ensure that you are not pregnant.

The night before or in the morning of the examination date, you will receive laxatives or a rectal enema in order to empty the large intestine for endoscopy. The rectal enema can be done either at home or at the hospital.

Then, a doctor will give you tranquilizer or pain killer orally or intravenously (free of charge) in order to reduce discomfort prior and during this process. You will be relaxed and sleepy after receiving the drug. The gastroenterologist will insert a GI endoscope with lubricant applied inside your anus followed by the release of some air inside the large intestine to look around the wall. The sigmoid biopsy will be performed by cutting small pieces (16-30 pieces) about the size of match head. Bleeding during the biopsy may occur and the doctor will stop that bleeding.

The overall process takes approximately one and a half hours. Afterwards, we will observe until you are fully awake and have no pain, or no bleeding. Observation time is approximately 3 hours.

Samples of the sigmoid biopsy will be stored to study your immune response to the vaccine. If there is any abnormality found, you will be transferred for appropriate treatment.

The study team will arrange for the transportation and accommodation. The study staff will accompany you on the way to and back from Chulalongkorn Hospital. 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 any expense.

3. Risks of Sigmoid Biopsy

You may feel exhausted as a result of the laxative or rectal enema.

You may feel uncomfortable or shy about the sigmoid biopsy collection. In order to reduce that feeling, all procedures will be performed in a special prepared room. This room will be set to make as much privacy as we can.

You may feel discomfort and cramping during the insertion of the GI endoscope and the release of air into the intestine. You may feel bloating and need to pass the gas. You can pass this gas any time to make you feel better. After the biopsy is complete, the doctor will release gas from the intestine as much as possible.

There may be bleeding during sigmoid biopsy sample collection which will be stop immediately during the GI endoscopy procedure.

There might be some risks of tearing of the large intestine wall and fluid and bacteria influx into the abdominal space which would require surgery and antibiotics. The treatment requires an overnight stay in the hospital. However, the chance of it is very slim.

After completion of the process, you may feel dizzy and sleepy as a result of the tranquilizer, so you should not drive to the clinical site for this visit.

4. Your benefits from sigmoid biopsy

You may not directly benefit from the sigmoid biopsy sample collection. However, the gastroenterologist will examine you for any abnormality in the sigmoid such as abnormal polyps or hemorrhoid which may require further appropriate treatment. In addition, this study data will provide the investigators with insight into the human immune system, HIV infection, and will be used for HIV-vaccine development in the future.

5. Compensation for sigmoid biopsy collection

You will be compensated for your time, travel expenses, and missed wages for travelling for each appointment for sigmoid biopsy sample collection in amount of 2,000 Baht (two thousand baht only).

6. Sigmoid Biopsy Sample Storage

Sigmoid 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 of Thailand.

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

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

7. Future Study

If you are willing, the sigmoid 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 must be reviewed and approved by the Ethical Committee or Institutional Review Board which oversee the medical study in order to protect rights and welfare of human volunteer.

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

Your 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 bring about 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 sigmoid biopsy sample 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 are able to 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 sigmoid biopsy collection

If you get sick or injured due to sigmoid 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 mucus sample collection. If you have any question about the illness or injury related to this sample collection, you can contact the Principal Investigator or designee, Punnee Pitisuttithum, MD, Tel: 08 1829 4906. 2) LTG. Sorachai Nitayaphan, Tel 08 1625 1531

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

You can withdraw from the sigmoid biopsy sample collection 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 sigmoid biopsy 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 question

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 works of the study staff, you can ask the Principal Investigator or the designee;

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