

Information Sheet for Additional Bone Marrow Aspiration 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 bone marrow aspiration, please read this document thoroughly. In doing so, you will acknowledge the 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 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

Bone marrow is tissue in our bone. Laboratory investigators can use bone marrow cells to study human health and diseases. Bone marrow is a source of several cells' generation such as red blood cells, platelets, and white blood cells. One type of white blood cell called "B-cell" acts as one of the types of cells that contribute to protect ourselves from infection. B-cell white blood cells in bone marrow may have different characteristics in comparison with those found in the blood and mucosal tissues such as our intestines. Understanding better these white blood cells

may benefit HIV vaccine development in the future.

This bone marrow aspiration is important to collect cells for evaluation of the immune cells response after receiving vaccination.

2. Bone Marrow Aspiration Process

Bone marrow aspiration will be collected from Group 2 only. There are approximately 10 participants for this process. This procedure will be performed in the 50th week. Sample collecting will be done at Chulalongkorn Hospital and Hospital for Tropical Diseases.

The investigator would like to draw additional 30 mL (2 table spoons) of your blood in the 49th week (one week prior to the procedure) and another 30 mL (2 table spoons) on bone marrow aspiration date. This will allow us to compare immune response between your blood and bone marrow.

For female participants, you will be tested for pregnancy before bone marrow aspiration to ensure that you are not pregnant.

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.

Before performing this procedure, you also be asked 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 procedure.

Bone marrow aspiration is done using a needle to pierce the bone and then withdraw a small amount of bone marrow. The location for the bone marrow aspiration is at the back of the hip bone. During the procedure, you need to lie still while lying face down. Bone marrow aspiration starts with cleaning the area to be pierced with antiseptic solution followed by the injection of an anesthetic drug. Then, the doctor will use a lancet to cut the skin to make a small opening at the area where the anesthetic drug was applied. A needle will be used to draw two mL (around half teaspoon) of bone marrow. The wound will be closed; it does not require sutures. The entire procedure will take approximately 20-30 minutes.

To perform this procedure, transportation will be organized by the study staff at no cost to the volunteer, and accommodation. Accommodation will be offered for volunteer's convenience and not for medical need as this procedure is done as outpatient procedure. The study staff will accompany you.

3. Risk of Bone Marrow Aspiration

Risks and discomforts include pain and tension at area where needle is applied. You may feel referred pain to your thigh. You may feel pain around the area of bone marrow aspiration for 2-3 days. You may experience the following severe symptoms, however, these rarely occur: hemorrhage, infection at bone marrow aspiration area, and allergy to local anesthesia. To mitigate these risks, an experienced and trained physician will perform the procedure at the King Chulalongkorn Memorial Hospital or Hospital for Tropical Diseases, in facilities and access to emergency or critical care whereas available.

You should not participate in bone marrow aspiration if you think you may pregnant. The investigator would like you to inform us if you are pregnant or plan to become pregnant.

4. Benefits you will receive from Bone Marrow Aspiration

You may not directly benefit from bone marrow aspiration. If there are any abnormalities found, you will be transferred for further appropriate treatment. 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 Bone Marrow Aspiration

You will be compensated for your time, travel expenses, and missed wages for an appointment for bone marrow aspiration in amount of 3,500 Baht (Three thousand and five hundred Baht only).

6. Bone Marrow Aspiration Storage

Bone marrow aspiration will be kept and labeled using a barcode with a numeric code so that 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 bone marrow 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, bone marrow aspiration 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 be approved by the Ethical Committee and the Institutional Review Board which oversee the medical study in order to protect rights and welfare of human subjects.

The investigator team may ask to study genetic characteristics of your white blood cell sample. Genetic study is conducted to better understand your immune responses to the vaccine.

These samples will be used for study purposes only. They will not be sold or purchased.

Results obtained from the study of your sample may result in 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 bone marrow 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 can withdraw your permission to store this sample 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 bone marrow aspiration

If you get sick or injured due to this bone marrow aspiration, 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 the illness or injury related to this sample collection, you can contact the Principal Investigator or the designee, Punnee Pitisuttithum, MD, Tel: 08 1829 4906, [2) *[LTG.Sorachai Nittayaphan, Tel 08 1625 1531]*

9. If you are not willing to participate in bone marrow aspiration

You can withdraw from this sampling 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 bone marrow aspiration

If you decide not to participate in bone marrow aspiration, 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 the study staff, you can ask the Principal Investigator or designee;

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The Armed Forces Research Institute of Medical Sciences, Thai party
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If you do not receive proper treatment for any injury or illness occur 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
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Royal Thai Army Medical Department Institutional Review Board
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Faculty of Medicine, Chulalongkorn University
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