Prof Angela M Minassian
E-mail: info@ovg.ox.ac.uk
Tel: 01865 611400
IRAS project ID: 1010837
NRES Committee: 25/SC/0053

PARTICIPANT INFORMATION SHEET

Additional information: Fine needle aspiration (FNA)

BIO-005: A study to assess the safety and effectiveness of two experimental malaria vaccines

Participants are invited to attend an optional visit for a "fine needle aspiration".

What is fine needle aspiration (FNA)?

Fine needle aspiration (FNA) involves taking cells and fluid from a lymph node (gland).

You will have an examination to feel for the glands in your armpit. An ultrasound scan will look closely for your lymph glands. Once a suitable gland has been identified, the area will be cleaned and numbed using local anaesthetic. Using the ultrasound scan for guidance, a needle will be used to collect a small amount of fluid and cells from the gland. You should not feel any pain but may feel some pressure. The sound waves used in ultrasound scans are safe. Ultrasound scans do not use any radiation, unlike in X-rays or CT scans. This procedure may be done on one or both armpits – the study team will discuss this with you. The whole visit can take 1-2 hours. The FNA procedure itself takes only a few minutes, and you will be observed for 30 minutes after the procedure.

FNA is commonly performed in outpatient clinics to help diagnosis in patients with different health conditions, for example, lumps or swollen glands. It will be performed by a doctor trained in the technique.

Why is this being done?

Immune responses to vaccination are typically tested by taking blood samples and measuring proteins called antibodies and immune cells (lymphocytes). However, the immune responses to vaccination mainly occur in the lymph glands. These are small bean shaped organs found throughout the body. Testing the lymph glands will help us understand more about how the body reacts to the vaccine and may help us predict how long the immune response induced by the vaccine lasts.

What are the risks of an FNA?

FNA is safe but, as with any medical procedure, it carries some risks:

- **Pain:** The FNA should not be any more uncomfortable than a blood test. Any tenderness afterwards will resolve. You can take a simple painkiller like paracetamol if you need it. Avoid taking aspirin, as this may increase the risk of bruising.
- **Bleeding:** The needle used is very slim but bleeding under the skin may sometimes occur after the FNA. It usually stops quickly by itself. Any bruising will fade within 2 weeks.
- **Infection** after FNA is rare. If you get redness, pain and/or tenderness in the days afterwards, you may need antibiotic treatment.
- **Damage to nearby tissues and organs**: it is possible for the needle used in an FNA procedure to damage underlying structures; however, such occurrences are extremely rare. Among these, a rare but potential complication of ultrasound-guided FNA of axillary (armpit) lymph nodes is a pneumothorax. This occurs when air leaks into the space between the lung and chest wall, which

can cause pain and, in some cases, difficulty breathing. A small pneumothorax can heal by itself with rest. To date, this complication has only been reported in a single case study and a separate clinical trial conducted at the University of Oxford. Fine needle aspiration procedures are conducted under ultrasound guidance to prevent this from happening.

If the doctor is not able to collect enough sample, they may decide to repeat the FNA with your permission. This may be either during the same visit or another visit may be arranged. You will be monitored throughout the procedure and for 30 minutes afterwards to assess for any of the risks mentioned above or any unusual symptoms. Before you leave, you will receive guidance on post-procedure care and be provided with a medical alert card containing a 24-hour study mobile number (07990139223).

In the 1st week after the FNA, one of the study doctors may call you to check if you are doing well since the procedure. They may ask you about any ongoing symptoms, such as pain and swelling, for example. If you experience any unusual, unexpected, or severe symptoms after you have left the facility or are in any way concerned, you should call the study doctor urgently for advice. Do not wait for them to call you. You can use the 24-hour study mobile number to contact the study doctors at any time. However, if you believe it is an emergency, please call 999 or attend your local emergency department.

What else will happen during the visit?

Before the procedure, your temperature, blood pressure, and pulse rate will be recorded. These may be repeated after the FNA procedure (including oxygen saturations if indicated) while the clinical team observe you in the clinic. You will also have a blood test during this visit. This is so we can compare the immune response in your glands with the immune response in your blood.

Do I have to have an FNA?

No. This visit is optional and doesn't affect your participation in the rest of the study.

Is there anyone who can't have an FNA?

Yes. There are certain people who will not be able to have an FNA even if they join the study.
You will not be able to have an FNA if you:

- Regularly take medication which thins the blood (anticoagulation or antiplatelet medication), such as aspirin, warfarin or clopidogrel;
- Have any medical conditions which mean that you bleed more than other people;
- Have a history of significant problems relating to your lymph glands;
- Are allergic to local anaesthetics, such as lidocaine; or
- Have previously had anaphylaxis from local anaesthetics, such as lidocaine.

We will ask you questions to find out if any of these apply to you.

When will the visit take place?

This visit will take place about 5 to 11 weeks after your final study vaccination (Group 1) and approximately 3 to 9 weeks after the malaria 'challenge' (Group 2). For Group 1, this will be approximately 7 to 9 months after enrolment. For Group 2, this will be approximately 1 to 3 months after enrolment. This visit will be combined with another planned study visit if possible.

What will happen to any samples or images from this visit?

Samples collected during the FNA will be analysed and stored in the same way as your blood samples. This is described in the **"What will happen to any research samples I give?"** section of the main study information leaflet.

Ultrasound images may also be stored in a pseudonymized form with your study number rather than your personal details on them. In the unlikely event of seeing any possible abnormalities on the ultrasound scan, the scan will be checked by a specialist. If the specialist feels that there is an abnormality that is important

to your health, we will discuss this with you and your GP, and they will arrange for further investigations if needed. It is important to note that scans are intended for research rather than assessing your health. If you have any concerns about your health, you still need to see your GP.

Will I be paid for this extra visit?

Yes. If you decide to attend the extra visit for the FNA, you will receive additional reimbursement for your time and inconvenience. This will be an extra £150.