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LEGACY02: Examining lymph node cells to assess how age affects immune responses

Core Needle Biopsy Cohort

RECRUITING NOW!

Dear Potential Study Participant,

This letter contains information regarding a new experimental medicine study:

Please read this carefully, and if you would like to participate let us know via the contact details below.

We are researching how people respond to new vaccines, and how this changes as we age.

Unfortunately, as we age our response to vaccines also changes and vaccinations tend to be less effective in the elderly. This study aims to better understand why this is the case, so we can tailor vaccines that can protect those most at risk.

To understand this process better, we are testing cells taken from lymph nodes (glands) after vaccination. Lymph glands are small bean shaped organs present all over the body. After a vaccine is given in the arm, the lymph glands in the armpits swell as, inside the glands, cells make antibodies in response to the vaccine. These antibodies protect us from infection after we have had a vaccine.

We aim to recruit up to 4 adults in this study cohort, aged either 18-45 years or 65 years and over

In this study you would have two doses (given 12 weeks apart) of a new vaccine against **Crimean-Congo haemorrhagic fever virus**. The vaccine is called **ChAdOx2 CCHF**. Cells from lymph glands can be sampled using a method called **core needle biopsy (CNB)** and it is a well-established test in the clinic. This allows us to look at cells in lymph glands directly. This information will help researchers design future vaccines, and decide how they are given to different populations, for example older people, to offer the best protection against disease.

A small incision, about the size of a grain of rice, will be made in the skin and a needle will be used to collect a small amount of tissue from the gland. An ultrasound scan is used as a guide during the procedure. The incision made will not require sutures and a dressing over the incision will be provided and will be expected to heal around 2 weeks without further problems. It should not affect your day-to-day activities but we will ask you not to perform any vigorous activity or heavy lifting for 24 hours after the procedure.

The study will also involve blood tests.

There will be a total of 6 study visits: 1 screening visit (to ensure eligibility), 2 study injections (vaccination) visits, 1 CNB visit, and 2 follow up visits. There will also be 1 follow up phone call. You will be followed up for 4 months after the first study injection.

You can, if you decide to (for whatever reason), withdraw from the study at any time (see main Participant Information Sheet for more details).

There is no risk of contracting Crimean-Congo haemorrhagic fever virus from the vaccine itself, and participants will not be exposed to the virus at any point during this study.

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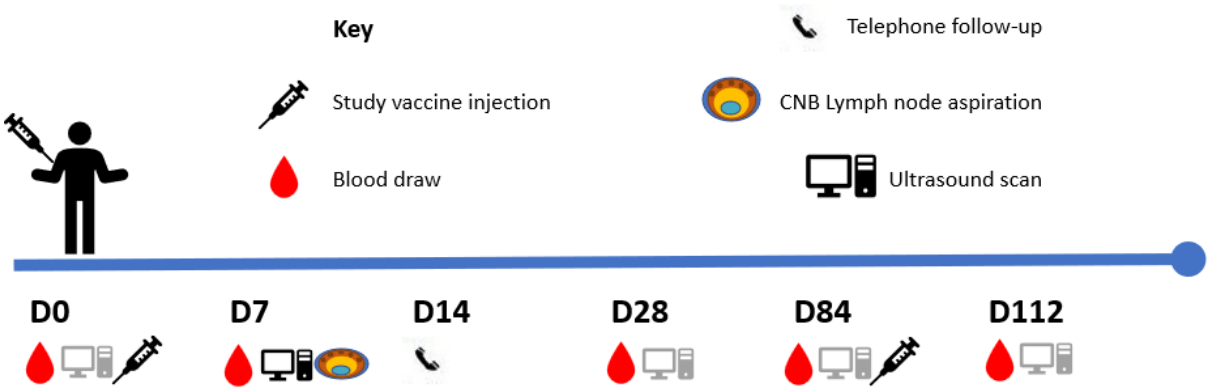
Who can take part?	Adults in good health 1. Aged either 18-45 years or 65 years and over
Study injections	Two doses of ChAdOx2 CCHF, 12 weeks apart, given as an injection in the arm.
Procedure	Lymph node cell sampling using core needle biopsy (CNB) of the armpit (on the side that received the vaccine) 7 days after the study injection
Study Aims	To investigate how age affects immune responses in lymph nodes to a new immunisation. To compare responses in older people with those in younger people. Core needle biopsy group only; to study the safety and tolerability of lymph node core needle biopsy after immunisation.
Chief Investigator	Dr Katrina Pollock
Principal Investigator	Dr Katrina Pollock
Study Site	Oxford Vaccine Group, University of Oxford, Centre for Clinical Vaccinology and Tropical Medicine, Churchill Hospital, Headington, Oxford, OX3 7LE
What happens in the study?	1. Volunteers will attend a screening visit, to decide their eligibility to take part, and to obtain their consent. 2. At the next visit, the study injection will be given 3. Any armpit or lymph node symptoms after the injections will be recorded in an electronic diary for 7 days. 4. Participants will have core needle biopsy (CNB) sampling 7 days after the first study injection. All participants will be followed up for 4 weeks including a follow-up phone call 2 weeks after the core needle biopsy. 5. Participants will then have their second study injection 12 weeks after first study injection, with an another follow up visit 4 weeks after second study injection. 6. Participants will attend a total of 6 study visits (1 screening, 2 injections, 1 CNB and 2 follow up visit) 7. All in person visits will include a blood test. The safety of participants will be closely monitored throughout the study.
Reimbursement	Screening visit: £110 Study Injections visit: £110 CNB visits: £175 per visit Follow up visit: £90 per visit Diary card: £30 per diary Total reimbursement (6 visits): £775
Risks of participation	After **CNB**, there may be some discomfort, bruising or bleeding. Very rarely infection may occur. These risks, along with potential rare complications, are detailed below (page 3).

	After **study injection,** short-lived symptoms may occur, such as fever and discomfort of the arm. The study injection has been made using similar technology to the Oxford-AstraZeneca Covid vaccine, which has been associated with rare disorders including abnormal blood clotting. A full discussion of risks, including potential rare but serious reactions, can be found on page 10.
Benefits of participation	By participating in this study, you will not directly receive any personal health benefit from the study or its procedures. However, you will be helping us to understand how immune responses to immunisation change with ageing. By taking part in this study, you will be helping to improve vaccines and benefit others in the future.

The diagram below shows the study visits.



Images in grey and all procedures listed at Day 42 represent **optional** interventions, and will be carried out depending on-site staff capacity and resources

Please read the full participant information sheet https://www.ovg.ox.ac.uk/studies/legacy02 carefully before deciding whether to participate.

If you have any additional questions about the study, please contact us at info@ovg.ox.ac.uk and/or 01865 611400.

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If you are interested in participating in this study:

You can either complete the online pre-screening questionnaire
https://www.ovg.ox.ac.uk/studies/legacy02

OR

E-mail us at: info@ovg.ox.ac.uk

OR

Telephone us on: 01865 611400