COHORT EVENTS MONITORING (CEM) STUDY FOR THE ASSESSMENT OF SAFETY PROFILE OF MVA-BN (JYNNEOS) VACCINE IN ADULT PERSONNEL AND STAFF IN THE PALM-007 STUDY IN DEMOCRATIC REPUBLIC OF THE CONGO

Informed Consent v2.0, 07Oct2023

NCT05734508

INFORMED CONSENT FORM

Title of the study	**Cohort events monitoring (CEM) study for the assessment of safety profile of MVA-BN (Jynneos) vaccine in adult personnel and staff in the PALM-007 study in Democratic Republic of the Congo**
Sponsor	**National Institutes of Health (NIH)/ Institut National de Recherche Biomédicales (INRB)**
Protocol Number	**PALM 008**
Principal Investigator	**Nsengi NTAMABYALIRO, MD, MSc, PhD** **+243815171991**
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PREAMBULE

As part of your work in the PALM-007 study, you will be in contact with patients with Monkeypox. This puts you at risk of contracting this disease. Vaccination against this disease is offered to you as well as participation in the study on the safety of this vaccine in Congolese adults involved in the PALM-007 study.

This form gives you information to help you decide whether or not to participate in the study. Participation in the study is voluntary. Please read this form carefully. You can ask all questions related to the study. You can then decide if you want to participate in the study.

KEY INFORMATION ABOUT THIS RESEARCH

Nature and objectives of the study

The general objective of this observational study is to monitor the safety of the MVA-BN (JYNNEOS) Monkeypox vaccine among personnel of the PALM-007 study in the DRC in order to assess its safety profile. It will also consist of collecting information on any adverse event that may arise after vaccination with the MVA-BN vaccine (JYNNEOS).

The MVA-BN vaccine is a live attenuated non-replicating smallpox vaccine formulated from live modified vaccinia Ankara viruses. It has been approved for prevention of smallpox and monkeypox infection.

If you qualify and sign informed consent, you will receive the recommended schedule which includes 2 doses of 0.5 mL MVA-BN vaccine injected under the skin paced at least 28 days apart**.**

Course of the study

Participation in this study is entirely voluntary, and recruitment is done after obtaining the written informed consent of the participants. After receiving the vaccine, you will be followed up for at least 56 days (up to the 28th day after the second dose of the vaccine). You may withdraw from the study at any time and for any reason, without disclosing the reasons for withdrawal. The withdrawal will not affect your current position in the PALM-007 study.

Pregnant and breastfeeding women will not be included in this study. For all women of childbearing potential, a pregnancy test will therefore be done at screening and on Day 28 before administration of the second dose of vaccine. If the pregnancy test on Day 28 is positive, the participant will not receive the second dose. In the event of a pregnancy occurring during the follow-up period (including a positive pregnancy test on Day 28), the pregnant woman will be followed. She will be requested to contact the study team to report any adverse event during the pregnancy. At delivery, information on the health status of the newborn will be shared with the study team and any adverse event reported.

Please note that infection control measures like avoiding close contact with the patients, wearing gloves, masks and other personal protective equipment may also help you to avoid infection with monkeypox.

If you wish to participate in this study, and after signing this form, you will receive two copies of the informed consent form. One of the copies will be given to you and the other archived by the investigator. Your contact information, your age, health status and medications will be collected, and physical examination performed.

If you are able to participate in this study (after clinical evaluation), we will administer two doses of the JYNNEOS vaccine; the first just after you have signed the informed consent, and the inclusion and exclusion criteria are verified and the second 28 days later. The administration of the vaccine will be done under the skin in your shoulder (left or right), and we will monitor you for at least 30 minutes to detect and manage any adverse events.

Participants will be asked to report adverse events of vaccination at several times during follow-up (on the day of vaccination, then on Days 3, 14 and 28 post vaccination). This follow-up schedule will also apply to the second dose. The follow-up can be done at your place of work (the Monkeypox treatment center in the PALM-007 study) or by telephone.

Study participants will be provided with contact information of vaccine research staff and have the right to contact the research team either directly or by phone if they have any questions about the side effects they may be experiencing or if they are concerned. Up to 1000 participants will be enrolled in the study.

Benefits

The main benefit is that the vaccine prevents Monkepox disease in persons who have been exposed or may become exposed to the Monkeypox virus.

If many people get the vaccine, it can also protect against infections in people at risk for serious disease.

However, this study is not intended to assess the efficacy of the vaccine. Only safety will be assessed.

Risks

Like any active product, the JYNNEOS MVA-BN vaccine can cause side effects. But these effects are often mild. Common adverse events include local events like redness, pain, swelling, itching, hyperpigmentation and induration, or general effects like fatigue, headache, pain in muscles, nausea, chills, fever, and flu-like symptoms. The frequency of adverse events, especially local site reactions, in people who have never been vaccinated against smallpox, and in people vaccinated for the first time (with MVA-BN), does not appear to be significantly higher than the frequency of adverse events in revaccinated people.

Complaints and compensation

If you experience any injuries or complications as a result of your participation in this study, you should contact the study team as soon as possible. The research team will assist you in implementing appropriate care. You will receive the appropriate care at the study site in the event of minor problems such as wounds or headaches; you will be transferred to an appropriate health institution in the event of a more serious problem.

You will be vaccinated at the workplace; no compensation will be provided for participation to this study. However, if there is a need for an unscheduled visit, compensation of $5 US will be provided to you for transportation. If you become pregnant during the study, the site may assist you in the fees related to antenatal consultation (a maximum of $5 for each) and ultrasounds (a maximum of $10 for each).

Voluntary participation and possibility of withdrawal

Your participation in this study is voluntary. If you are not interested in participating or you decide to withdraw from the study, your current position will not be affected.

Privacy

During your participation in this study, all information obtained, including your medical history and physical examination will be kept strictly confidential within the limits provided by law. In order to preserve your identity and the confidentiality of the information, you will only be identified by a code number. The code key linking your name to your research file will be kept by the responsible researcher.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Website at any time.

Resource persons

If you have any questions about the research project or if you have a problem that you believe relates to your participation in the research project, you can contact the researcher in charge of the research project at the following numbers – Dr Nsengi Ntamabyaliro : +243815171991; Dr Aline Engo: +243998863986 or +243821631485.

For any questions regarding your rights as a subject participating in this research project or if you have any complaints or comments to make, you can contact the Ethics Committee of the School of Public Health in Kinshasa at the following number: Prof Darius Makindu: +243852366376

Monitoring of the ethical aspects of the study

The Ethics Committee of the Kinshasa School of Public Health approved this study and is monitoring it. In addition, this Ethics Committee will approve in advance any revision and any modification made to the information and consent form and to the research protocol.

CONSENT TO RECEIVE JYNNEOS VACCINE

☐ I freely agree to participate in this research study as described and understand that I am free to withdraw at any time during the study without affecting my position in the PALM 007 study.

☐ I have read the informed consent form. I acknowledge that the project was explained to me, that my questions were answered and that I was given enough time to make a decision.

☐ I confirm that I have received and understood the information provided to me on the JYNNEOS vaccine and agree to receive a full course of the JYNNEOS vaccine.

Name of Participant _____

Signature _____ Date _____

IMPARTIAL WITNES

Name of Witnes _____

Signature _____ Date _____

DECLARATION BY STUDY DOCTOR

I have given a verbal explanation of the research study, its procedures and risks and I believe that the participant has understood that explanation.

Name of Study Doctor _____

Signature _____ Date _____