



INFORMATION FOR THE PUBLIC

University of Tokyo

MV-NiV

MV-NiV will be assessed in the clinical study 2025-522293-37-00 entitled: *A Phase 1, placebo-controlled, randomized, participant- and assessor-blind, single-center study to assess the safety and immunogenicity of 2 dose levels of Nipah measles vector (MV-NiV) vaccine administered subcutaneously either as a single dose or as 2 consecutive doses at 4-week interval, in healthy non-exposed volunteers, aged 18-40 years.*

Deliberate Release Reference Number
B/BE/25/BVW6

The release of genetically modified organisms (GMOs) in the environment is strictly regulated at European level by Directive 2001/18/EC and at Belgian level by the Royal Decree of 21 February 2005.

To ensure safe use of GMOs, the provisions of the Royal Decree of 21 February 2005 stipulate that the release of GMOs for experimental aims is prohibited without prior consent from the competent Minister. The decision is based on a thorough evaluation of the biosafety of the planned release, which is conducted by the Biosafety Advisory Council, composed of different Scientific Committees grouping independent experts from Belgian universities and governmental institutes.

To acquire the necessary authorization from the competent Minister, the University of Tokyo submitted an application dossier to the competent authority. On the basis of the advice of the Biosafety Council, the competent Minister could grant a permission to the University of Tokyo to conduct experiments with the genetically modified organism MV-NiV as stipulated in the application B/BE/25/BVW6.

The release will take place at one hospital in Flanders:

- Centre of Vaccinology (CEVAC), Ghent

The clinical study 2025-522293-37-00, in the context of which the release will take place, is expected to start in January 2026. Recruitment and vaccinations are planned to begin at that time. Each participant will be closely monitored for about 6 months, with regular clinic visits to check their health. The study is expected to conclude in March 2028.

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GENERAL INFORMATION

Description of the Genetically Modified Organism (MV-NiV)

The genetically modified organism (GMO) used in this study is called live attenuated virus (or 'LAV') – MV-NiV.

LAV-MV-NiV is made by genetically modifying a weakened (or attenuated) version of the measles virus, known as the Edmonston strain. This measles strain has been used safely in vaccines around the world for decades and has helped protect millions of people from measles. Because of its long history of use, we know a lot about how this virus behaves in the human body:

- The measles virus used in the MV-NiV vaccine can multiply temporarily inside the body after vaccination. A small amount of the virus may be detectable in the blood or tissues for a short time. However, once the body starts to produce antibodies, those antibodies quickly recognize and eliminate the virus.
- This attenuated measles virus cannot be spread from person to person under natural conditions. It does not survive in the environment and is not passed on through coughing, sneezing, or touching.
- The only theoretical way someone else could be exposed would be through direct contact with blood or biological materials from a vaccinated person (e.g. through transfusion, organ donation, or pregnancy), but this risk is considered very low.
- The virus is fragile and cannot survive for long periods outside the human body. It is easily destroyed by heat, dryness, sunlight, and standard disinfectants.

To make the MV-NiV vaccine, scientists have added the genetic code for a specific surface protein from the Nipah virus, called the G glycoprotein (NiV-G), into the measles virus. This protein is found on the outside of the real Nipah virus and is what the virus uses to attach to cells in the body.

When a person is vaccinated with MV-NiV, their body not only responds to the measles virus, but also produces antibodies against the Nipah virus G protein. This means that if the person ever comes into contact with the real Nipah virus, their immune system will be prepared to recognize and fight it off.

The NiV-G protein by itself cannot cause Nipah virus infection. It is not capable of entering cells or spreading on its own. It is simply used to "train" the immune system to recognize and neutralize the real virus if needed.

The goal of this genetic modification is to help the body develop protection against Nipah virus, using a well-known and safe measles virus as a delivery tool.

Description of the Vaccine (MV-NiV)

The MV-NiV vaccine is given as a live, weakened virus. It is based on the measles vaccine virus, which has been safely used around the world for many years. For this vaccine, scientists have added a small part of the Nipah virus—a protein called G—into the measles virus. This added protein helps the immune system recognize and protect against Nipah virus, but it cannot cause Nipah disease. After the vaccine is given, the virus may briefly multiply in the body, which helps the immune system learn to defend against it. This is normal and expected. The immune system quickly responds by making antibodies, and the virus disappears.

The MV-NiV vaccine is not made from DNA and cannot spread in the environment. It does not survive outside the body, and it cannot be passed to others.

RESEARCH / DEVELOPMENT ACTIVITIES

Previous Development Activities

Preclinical development activities have focused on:

- Developing a manufacturing process to allow production of high-quality MV-NiV vaccine in sufficient quantity for human clinical trials;
- Demonstrating the safety, immunogenicity and protective efficacy of the vaccine in relevant animal models. In particular, animal studies showed that MV-NiV induces high levels of antibodies able to neutralize the Nipah virus and protects against Nipah disease cause by Malaysian and Bangladeshi strains of the virus. Also, safety studies showed that MV-NiV is well tolerated and has a safety profile comparable to that of commercial M-M-R® II vaccine.

Future Activities: First in Humans Clinical Study

The MV-NiV vaccine will be tested in humans for the first time in a clinical study called:

“A Phase 1, placebo-controlled, randomized, participant- and assessor-blind, single-center study to assess the safety and immunogenicity of 2 dose levels of Nipah measles vector (MV-NiV) vaccine administered subcutaneously either as a single dose or as 2 consecutive doses at 4-week interval, in healthy non-exposed volunteers, aged 18-40 years ”

The main goal of this study is to make sure the vaccine is safe and that it triggers an immune response in humans.

The release will take place at one hospital in Flanders: **the Center of Vaccinology (CEVAC)**, University Hospital Ghent, C. Heymanslaan 10, 9000 Ghent, Belgium.

A total of **60 healthy adult participants** will be enrolled in Belgium, randomized into four groups of 15 participants each.

Some will receive placebo, and others will receive one or two dose levels of the MV-NiV vaccine at different strengths (1,000 or 10,000 infectious units, called TCID₅₀). The study uses a step-by-step (dose-escalation) approach: if the lower dose level is safe, the next group will receive a higher dose level.

During the study, doctors will:

- Monitor safety by checking for side effects and general health.
- Test for the presence of the virus in blood and other samples to see how the body handles the vaccine.
- Measure immune responses, including the production of antibodies and other defense cells against the Nipah virus.

Recruitment and vaccinations is planned to start in **January 2026**. Each subject will be closely followed for about 6 months, with regular clinic visits to check their health. The overall study is expected to **conclude by March 2028**.

This study is an important first step in developing a safe and effective vaccine to protect people from Nipah virus disease, a serious condition with no approved vaccine or treatment.

POTENTIAL BENEFITS

The goal of the MV-NiV vaccine is to help the body make antibodies and immune cells that can protect against Nipah virus. The vaccine uses a weakened measles virus that has been modified to include a small part of the Nipah virus, called the G glycoprotein. This protein helps the immune system recognize the virus, without causing the disease.

Nipah virus is a dangerous virus that can infect both animals and humans. People usually become infected through contact with infected animals, such as bats or pigs, or sometimes from other infected people. After infection, Nipah virus can cause severe illness, including fever, confusion, seizures, and swelling of the brain. In many cases, the disease can be deadly, with no specific treatment available.

There is currently no approved vaccine for Nipah virus. If an outbreak happens, there are very few tools to stop it. That's why scientists are working to develop safe, effective, and affordable vaccines like MV-NiV—to help protect people in countries where the virus might spread, and to be better prepared for future outbreaks.

POTENTIAL RISKS

Potential Risks for Human Health Linked to the Deliberate Release

The MV-NiV vaccine is made from a weakened measles virus that has been used safely in vaccines for decades. Like the measles vaccine virus, MV-NiV cannot naturally spread from one person to another. It does not travel through the air or spread through coughing or sneezing.

The only ways that MV-NiV could theoretically spread to someone else are:

- If a member of the clinical staff accidentally gets vaccinated, for example through a needle-stick injury, or if they are exposed to a blood or body fluid sample from a vaccinated person and it comes into contact with a cut or graze.
- If someone were to receive a blood transfusion or organ transplant from a person who recently received the vaccine.
- If a pregnant woman is vaccinated and the virus reaches the unborn baby, or if she is breastfeeding her child.

These situations are very unlikely, especially because the clinical trial has strict safety measures in place to prevent them. For that reason, the risk that MV-NiV would accidentally spread to someone else is considered low to negligible. If someone were to be accidentally exposed and infected with MV-NiV, the potential risks would be the same as those seen after vaccination. These could include:

- Mild side effects like headache, tiredness, muscle aches, fever, or chills. These are common with vaccines and go away on their own.
- Rare but more serious side effects are possible, but very unlikely, just as with regular measles vaccines. So, the risk of mild side effects is low to moderate, and the risk of serious side effects is low to negligible.

There is also a theoretical risk that the virus could slightly change (mutate) inside the body, but this is very unlikely because the measles virus used in MV-NiV is known to be genetically stable. Another theoretical risk is that MV-NiV could mix with another similar virus, like the regular measles virus, to create a new version of the virus. But this would only happen if both viruses are present in the body at the same time—which is extremely unlikely, especially since the study is being done in Belgium, where these viruses are not circulating, and no live measles vaccines are planned during the study.

If someone with a weakened immune system (such as an infant or immunocompromised person) were accidentally exposed, the risks would be the same, but the chances of side effects might be slightly higher, because their bodies may not clear the virus as quickly.

Potential Risks for the Environment Linked to the Deliberate Release

The MV-NiV vaccine is made from a weakened measles virus that cannot survive outside the human body. It is very fragile and is quickly destroyed by heat, dryness, sunlight, and common disinfectants. This means that if small amounts of the virus were to enter the environment—for example, through

urine, stool, or other waste from a vaccinated person—there is no risk to the environment. The virus would not stay active and would not be able to infect people, animals, or plants. As a result, there are no environmental safety concerns related to the release of MV-NiV.

CONTAINMENT, CONTROL AND MONITORING MEASURES

Measures to Limit the Risks for Human Health

Although it is very unlikely that the MV-NiV vaccine virus could accidentally spread to people who are not part of the clinical study, several important safety measures are in place to completely avoid this:

- Hospital staff involved in the study will be properly trained. The MV-NiV vaccine will be prepared inside a biosafety cabinet, and staff will wear protective clothing, such as lab coats. If there is any accidental spill of the vaccine or a biological sample from a participant, the area will be cleaned with disinfectant (e.g. freshly prepared bleach/Javel). All materials that may contain the virus will be disposed of as hazardous medical waste.
- Participants in the study are not allowed to donate blood or organs for 3 months after their last vaccination. They must also take precautions to avoid pregnancy (1 month for men and 6 months for women) after vaccination (this includes both male and female participants). Women cannot take part if they are pregnant or breastfeeding.
- Although MV-NiV does not naturally spread from person to person, we want to avoid even a small theoretical risk to people with a weakened immune system. For that reason, participants may not live with or care for anyone who is immunocompromised or an infant under 6 months of age for at least 28 days after vaccination.

These steps help ensure that the vaccine stays completely contained within the study and that there is no risk to the wider public.

Measures to Limit the Risks for the Environment

If the MV-NiV vaccine or a sample (such as blood or urine) from a person in the study is accidentally spilled, the area will be immediately cleaned with a chemical disinfectant, such as freshly prepared Javel (bleach). Since the MV-NiV virus is very fragile and cannot survive in the environment, no additional measures are needed. The virus is easily destroyed by disinfectants, heat, dryness, and light, and cannot infect animals or spread through water, air, or soil. Therefore, there are no environmental risks if a spill occurs.

Emergency Situations

If a member of the hospital staff working on the clinical study accidentally self-administers the MV-NiV vaccine (for example, through a needle-stick injury), they must immediately report the incident to the responsible study physician or supervisor. The situation will be documented and followed up according to standard safety procedures. If the MV-NiV vaccine or a biological sample from a study participant (such as blood or urine) is accidentally spilled, the affected area will be immediately disinfected using freshly prepared Javel (bleach) to ensure complete inactivation of the virus. All contaminated materials will be disposed of as hazardous medical waste.

GLOSSARY

Biological sample. Sample of material that is collected from a living organism, for instance blood, urine or stool samples.

DNA. Genetic material. DNA is made of nucleotides. Each 3 nucleotides make up a codon. The codon can be translated into an amino acid. Proteins are made from amino acids.

Clinical Study. A research study to test an intervention (for instance a medicine or a vaccine) in people.

First in human clinical study. A clinical study in which an intervention is tested for the first time in people.

Genetically modified organism. An organism (microbe, plant or animal) whose genetic code has been changed using genetic engineering techniques.

Genetic code. The order of the nucleotides in DNA or in RNA.

Immune cells. The cells of the body's natural defense mechanism. Immune cells include cells producing antibodies but also other cells that help the antibodies to destroy foreign organism such as viruses.

Virion. A complete virus particle.

Virus. A very small (not visible for the naked eye) organism or microbe, that can infect and multiply in the cells of other organisms such as animals or humans.

CONTACT

If you have any comments on the public dossier or our activities or which to get additional information on the deliberate release of MV-NiV, you can contact us at:

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