

MERS coronavirus candidate vaccine gears up for clinical trials

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MERS coronavirus particles (green) on camel epithelial cells. Credit: NIAID in collaboration with Colorado State University.

Researchers from Ludwig-Maximilians-Universitaet (LMU) in Munich

have demonstrated, in a preclinical setting, the protective effect of a candidate vaccine directed against the coronavirus that causes Middle East Respiratory Syndrome. Planning for the first clinical trial is now underway.

Currently, no protective vaccine is available against the coronavirus strain responsible for Middle East Respiratory Syndrome (MERS). The need for such a vaccine is underlined by the current outbreak of the disease in South Korea, which has led to the infection of over 150 people and has already caused several deaths. Two years ago, a team of researchers led by Professor Gerd Sutter, who holds the Chair of Virology at LMU's Institute for Infectious Diseases and Zoonoses, reported that it had developed a candidate vaccine directed against the MERS-CoV. Further preclinical tests have confirmed its efficacy, as the team now reports in the *Journal of Virology*. These results lead the way for Phase I clinical trials, which will determine how well the vaccine is tolerated by human subjects.

The vaccine candidate, named MVA-MERS-S, was developed by Sutter's group in collaboration with colleagues based at Marburg University and the Erasmus Medical Center in Rotterdam. It is based on the use of a safety tested [vaccine](#) virus, the Modified Vaccinia virus Ankara (MVA). Essentially, MVA serves as a vehicle for an immunogenic antigen derived from the MERS-CoV. Using molecular biological techniques, Sutter's team have altered the structure of the MVA genome in such a way that genetic information coding for proteins characteristic of other viral pathogens can be spliced into it. The modified virus is then able to synthesize the foreign protein and displays it on the surface of infected cells. Once there, it can be recognized by cells of the immune system, which are stimulated to produce antibodies and T cells against it. In this particular case, the researchers used this system to express the so-called spike glycoprotein (protein S) specific for MERS-CoV.

Efficacy and safety verified

"We have now shown for the first time that MVA-MERS-S effectively induces protective immunity against MERS-CoV in a mouse model," explains Dr. Asisa Volz, a member of Prof. Sutter's group and first author on the new study. In earlier assays, the researchers had confirmed the immunogenicity of their [candidate vaccine](#) in cell culture, and demonstrated that it elicits the production of protective levels of MERS-CoV-neutralizing antibodies.

For the work now reported in the *Journal of Virology*, the team used a mouse strain that had been genetically modified to make it susceptible to infection with MERS-CoV. Following immunization with MVA-MERS-S, the mice were exposed to different doses of MERS-CoV. Subsequent tests revealed that, in mice that had received high doses of MERS-CoV, virus replication was markedly impaired, and the numbers of virus genomes in lung tissue were correspondingly reduced relative to the levels in non-immunized mice. "This demonstrates that our [vaccine candidate](#) is both safe and effective. Thus, there is no obvious risk that the resulting immune response might exacerbate rather than prevent the infection," says Gerd Sutter.

MVA-MERS-S therefore meets important criteria for use in clinical tests on human subjects. Indeed, the German Center for Infection Research (DIFZ) has already made a grant of approximately 1.5 million euros available for the project "GMP Manufacture and Phase I Clinical Investigation of MVA-MERS-S, an Experimental Prophylactic Vaccine against the Middle East Respiratory Virus Syndrome," which will be led by Gerd Sutter.

Infection with MERS-CoV initially causes flu-like symptoms, but the condition can progress to a full-blown respiratory illness, which may ultimately be lethal. The virus was first recognized in 2012 when it

emerged in Saudi Arabia. The present outbreak in South Korea is the largest so far recorded outside the Middle East. The index patient in this case was a man who fell ill after returning from a business trip to the Arabian Peninsula. Several patients who had been infected with MERS while visiting the Middle East have also been treated in Germany in recent years.

More information: "Protective efficacy of recombinant Modified Vaccinia virus Ankara (MVA) delivering Middle East Respiratory Syndrome coronavirus spike glycoprotein." *Journal of Virology* (May 2015), [DOI: 10.1128/JVI.00614-15](https://doi.org/10.1128/JVI.00614-15)

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