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Clinical trials of VPM1002 as a tuberculosis vaccine in newborns

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The only tuberculosis vaccine currently approved, the Bacillus Calmette-Guérin (BCG) vaccine, protects children from the most severe forms of the disease in most cases but does not provide protection against the most common form, pulmonary tuberculosis in adults and children. BCG has therefore been unable to contain tuberculosis worldwide. Scientists led by Stefan Kaufmann of the Max Planck Institute for Infection Biology in Berlin are therefore working feverishly on a more effective replacement for BCG. The vaccine candidate they have developed, dubbed VPM1002, will now be tested in a large-scale phase II trial with newborns. VPM1002 is a genetically modified variant of the Bacillus Calmette-Guérin (BCG) vaccine. Moreover, another trial will test whether VPM1002 is effective in the treatment of cancer of the bladder.

BCG was developed in 1921 and has since been the only available vaccine against tuberculosis. It consists of weakened Mycobacterium bovis bacteria, the causative agent of bovine tuberculosis, which is also transmissible to humans. The vaccine primes the immune system to fend off an infection due to Mycobacterium tuberculosis bacteria, the causative agents of tuberculosis in humans.

VPM1002 is based on the BCG vaccine. The Mycobacterium bovis bacteria it contains have been genetically modified and provided with a gene that makes it easier for the vaccine to be recognized by cells of the immune system. The vaccine should be more effective at protecting vaccinees from infection with Mycobacterium tuberculosis bacteria. VPM1002 was developed by a group headed by Stefan Kaufmann,

Director of the Max Planck Institute for Infection Biology. It is produced by the Serum Institute of India, the world's biggest manufacturer of vaccines in terms of volume. The company is sponsoring the development of VPM1002 in South Africa as a tuberculosis vaccine with the support of Vakzine Projekt Management GmbH (VPM) in Hanover.

The vaccine candidate has already been successfully tested in newborns in two clinical phase I and one clinical phase IIa trial in Germany and South Africa. Now newborn babies of HIV-positive and HIV-negative mothers will be vaccinated with VPM1002 at four clinics in South Africa, and the protection conferred against tuberculosis will be compared with that of BCG. The first vaccination is scheduled for April 2015.

Because BCG is also used as an immunotherapeutic agent against cancer of the bladder, it is also planned to test the efficacy of VPM1002 against this form of cancer. An application for the first clinical trial with VPM1002BC for the treatment of nonmuscle invasive bladder cancer was submitted in December 2014. The SAKK 06/14 trial is being sponsored by the Swiss Working Group for Clinical Cancer Research with support by VPM. The first patient will be treated with VPM1002BC in May 2015.

Provided by Max Planck Society