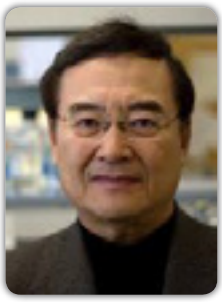

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Genetically modified and killed whole-HIV vaccine is safe and stimulates anti-HIV antibody responses in human

Development of efficacious vaccine to prevent HIV infection has been one of major tasks in the last three decades. We report here an evaluation of the safety and the immunogenicity of a genetically modified and killed whole-HIV-1 vaccine designated as SAV001. HIV-1 Clade B NL4-3 was genetically modified by deleting the *nef* and *vpu* genes and substituted the coding sequence for the Env signal peptide with that of honeybee melittin signal peptide in order to generate a replication efficient and attenuated HIV-1. This genetically modified virus (*gm*HIV-1NL4-3) was propagated in the human T cell line, A3.01, followed by virus purification and inactivation by aldrithiol-2 and γ-irradiation. Thirty-three HIV-1 positive volunteers receiving cART were recruited for this observer-blinded, placebo-controlled phase I human clinical trial to assess the safety and immunogenicity. The humoral immune responses were assessed by standard antibody ELISA and by neutralization assay of HIV-1. We found SAV001 was well tolerated with no serious adverse events. HIV-1_{NL4-3} specific PCR showed no evidence of vaccine virus replication *in vitro* and in the participants receiving SAV001 vaccine. Furthermore, SAV001 with adjuvant significantly increased the pre-existing antibody response to HIV-1 proteins. Antibodies in the plasma from these vaccinations were also found to recognize HIV-1 envelope protein on the surface of infected cells as well as showed an enhancement of broadly neutralizing antibodies inhibiting tier I and II of HIV-1 A, B, and D subtypes. Our results indicate that the killed whole-HIV vaccine is completely safe and may trigger appropriate immune responses to prevent HIV infection. This killed whole-HIV vaccine strategy may pave the way to develop an effective HIV vaccine.

Speaker Biography

C Yong Kang, PhD, DSc, FRSC, is a Molecular Virologist and Professor of Virology in the Department of Microbiology and Immunology, Schulich School of Medicine and Dentistry at the University of Western Ontario in Canada (1992-Present). He carried out his Postgraduate studies at McMaster University where he received a PhD in Virology under the supervision of Professor Ludvik Prevec (1968-1971) and his Post-doctoral training under Professor Howard Temin at the University of Wisconsin-Madison (1971-1974). He went on to serve as a Professor of Virology in the Department of Microbiology at the University of Texas, Southwestern Medical School in Dallas, Texas (1974-1982), Professor and Chairman of the Department of Microbiology and Immunology at the University of Ottawa, Faculty of Medicine (1982-1992), and Dean of Science at the University of Western Ontario (1992-1999). He has received numerous prizes such as the Award of Excellence of the University of Ottawa (1991), Gold Medal for Ilchun Lecture (1998), Ho-Am Prize in Medicine (1999), the Order of Korea in Science and Technology (2002), the McMaster University Distinguished Alumni Award for 2007, the Lifetime Achievement Award from University of Western Ontario (2009), the Queen Elizabeth II Diamond Jubilee Medal (2012), selected as a Korean-Canadian Diaspora to Canadian Society by Canadian Government (2013) and the Scientist of the Year Award from the Korean Federation of Science and Technology (2013). Dr. Kang was elected as a Life-time Fellow of the Royal Society of Canada Academy of Science (1993) and an elected Life-time Member of the Korean Academy of Science and Technology (1997). He continues to serve as a Grant Selection Committee Member for various federal granting agencies in Canada and the United States. He is a member of the Board of Directors of numerous research institutions and foundations. He also serves as a Reviewer for the *Journal of Virology, Journal of Infectious Diseases, Virus Research, Virology, Journal of Biological Chemistry, Journal of Human Virology and Retrovirology, and Canadian Medical Association Journal.*

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