

Poster presentation

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## **PI4-15 LB. The safety and immunogenicity of HIV-1 vaccines based on DNA and replication competent vaccinia vector in phase I clinical trial**

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from AIDS Vaccine 2009  
Paris, France. 19-22 October 2009

Published: 22 October 2009

*Retrovirology* 2009, **6**(Suppl 3):P404 doi:10.1186/1742-4690-6-S3-P404

This abstract is available from: <http://www.retrovirology.com/content/6/S3/P404>

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### **Background**

To assess the safety and immunogenicity of recombinant HIV vaccines of DNA and replicating competent Tiantan vaccinia (rTV)vector, the small pox vaccine used in China.

### **Methods**

HIV-1 CN54 gag, pol and env genes were constructed into DNA and rTV vectors. 48 healthy participants were either inoculated with rTV ( $5 \times 10^4$  pfu, skin scratches) or DNA vaccine (2 mg, 4 mg, i.m.) alone, in combination, or placed on the placebo. The participants were monitored up to 36 weeks for clinical symptoms and laboratory tests. Vaccine induced immunogenicity were measured by ELIs-pot, ICS, and antibody assays.

### **Results**

Typical skin reaction in all rTV vaccinated 24 subjects, enlargement of the lymph nodes under the same arm receiving rTV (12 cases) and slight fever (37.2 for 1 day, 1 case) were observed. No severe adverse events related to the vaccines were found. In rTV single vaccination group, positive IFN-g ELIspot was detected only in 6 of 7 vaccinia naïve subjects. In DNA/rTV group, T cell responses were detected in 15/16 (IFN-g ELIspot) and 16/16 (ICS) of vaccinia naïve and 5/6 (IFN-g ELIspot) and 5/6 (ICS) of vaccinia experienced. The responses of CD4 cells were higher than those of CD8 cells (100% versus 44%) and responsive rates to IL-2 and IFN-g were similar. HIV-1 gag and

env antibodies were detected only in the DNA priming and rTV boost groups and mainly among vaccinia naïve people (13/16 in naïve and 1/6 in experienced). Both T cell and antibody responses maintain by the end of the study at week 36.

### **Conclusion**

The vaccines are well tolerated and safe. It can stimulate HIV-1 specific T cell response in a single rTV vaccination and both T cell and antibody responses in DNA prime rTV boost. The vaccines are currently moving to phase II clinical trial in China.