Retrovirology

Poster presentation

P14-15 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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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 × 104 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 ELIspot, 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.