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A phase 1 clinical trial of Hantaan virus and Puumala virus M-segment DNA vaccines for hemorrhagic fever with renal syndrome delivered by intramuscular electroporation

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Hemorrhagic fever with renal syndrome (HFRS) is caused by infection with the Hanta viruses Hantaan (HTNV), Seoul (SEOV), Puumala (PUUV), or Dobrava (DOBV) viruses. We developed candidate DNA vaccines for HFRS expressing the envelope glycoprotein genes of HTNV or PUUV and evaluated them in an open-label, single-center phase 1 study. Three groups of nine subjects each were vaccinated on days 0, 28 and 56 with the DNA vaccines for HTNV, PUUV, or mixture of both vaccines using the Ichor Medical Systems intramuscular electroporation delivery device. Each vaccination consisted of 2.0 mg DNA in an injected volume of 1 mL saline. There were no study-related serious adverse events. Neutralizing antibody responses were detected in 5/9 and 7/9 individuals who completed all three vaccinations with the HTNV or PUUV DNA vaccines, respectively. In the combined vaccine group, 7/9 of the volunteers receiving all three vaccinations developed neutralizing antibodies to PUUV. The three strongest responders to the PUUV vaccine also had strong neutralizing antibody responses to HTNV. These results demonstrate that the HTNV and PUUV DNA vaccines delivered by electroporation separately or as a mixture are safe. In addition, both vaccines were immunogenic, although when mixed together, more subjects responded to the PUUV than to the HTNV DNA vaccine, suggesting immunological interference. Consequently, we have developed an optimized HTNV DNA vaccine that shows no interference in hamsters when mixed with the PUUV vaccine. Additional clinical testing of this new bivalent formulation is currently in progress.

Biography

Connie S Schmaljohn is the U.S. Army Senior Research Scientist for Medical Defenses against Infectious Diseases. Her studies focus on the development of molecular vaccines for biodefense, and on the molecular biology of highly pathogenic viruses.

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