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Conjugate rPA-PGA anthrax vaccine induces protective antibodies

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Anthrax is a lethal infectious disease caused by *Bacillus anthracis*. The two major virulence factors of B. *anthracis* are the poly-γ-D-glutamic acid (PGA) capsule and the exotoxin. Three components of the exotoxin form two bipartite toxins causing edema and organ failure. The anti-phagocytic PGA capsule disguises bacilli from macrophages, allowing unimpeded growth in the host. PA is a target of anthrax vaccine development as it elicits a toxin-specific protective immune response. However, PA based anthrax vaccines only address toxin-induced disease and not capsule mediated virulence. Recent effort has been to include PGA in 2nd generation anthrax vaccines, resulting in a promising vaccine providing comprehensive protection. Antibody to PGA fully neutralizes the capsule but PGA must be conjugated to a carrier protein to provide immunogenicity against both antigens. We have undertaken advanced development of an rPA-PGA conjugate vaccine for adult and pediatric populations. Our hypothesis is that by targeting the two virulence factors of B. *anthracis*, we can create an anthrax countermeasure that is more comprehensive and efficacious than currently available vaccines. We have shown by ELISA that our conjugate vaccine candidate produces significant levels of antibody to PA and PGA in mouse and rabbit immunogenicity studies. Compared to the approved anthrax vaccine, antibodies produced in response to the rPA-PGA vaccine are more protective in the toxin neutralization assay. Based on these findings, we proposed our conjugate vaccine and it would show protective efficacy in a lethal rabbit challenge model and would show non-inferiority to the current FDA approved anthrax vaccine. We have produced cGMP vaccine and performed a challenge study in New Zealand white rabbits with this vaccine lot. Our conjugate vaccine afforded 100% protection against lethal aerosol B. *anthracis* Ames strain spore challenge in vaccinated rabbits and all negative control animals succumbed to infection as expected within 2-3 days.

Biography

Hyeon U Park is currently Director of Product Development and Manufacturing at Biologics Resources LLC (BRLLC). He has his expertise in Microbiology, Protein Chemistry and Cancer Biology and has made contributions to "Translational research of prostate cancer at Georgetown University, virus-induced cellular transformation at NIH, manufacturing and characterization of conjugate vaccine at BRLLC". The current ongoing research projects at BRLLC include work on biodefense vaccines and therapeutics.

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