



## Pseudomonas Vaccine : from Bench to Beside

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**P***seudomonas aeruginosa* is an opportunistic human pathogen causing fatal nosocomial infections in hospitals. *P. aeruginosa* infects people with a defective immune system due to severe burns, cystic fibrosis, immunosuppressive or cancer chemotherapy. More than 90% of cystic fibrosis patients die of lung damage resulting from recurrent lung infections with *P. aeruginosa*. In patients with severe burn wounds or immunosuppressive therapy, the regional colonization with *P. aeruginosa* leads to systemic infection, causing septic shock. Due to intrinsic resistance to commonly used antibiotics and high occurrence of resistant strains, *P. aeruginosa* has emerged as one of the most important pathogens in hospital leading to a high mortality. Accordingly, development of an effective prophylactic and/or therapeutic vaccine for *Pseudomonas* has been urgently requested.

We have developed a *Pseudomonas* vaccine of outer membrane (OM) proteins free from LPS. To achieve a wide range of protection, OM proteins prepared from four attenuated *P. aeruginosa* strains were mixed in equal amounts and used as a vaccine, which elicited in rabbits a high titer of antibody reactive to all of the seven Fisher types. The experimental data on pre-clinical tests confirmed the safety and prophylactic efficacy of the vaccine.

The aim of the Phase I/IIa clinical trials was to evaluate the safety and immunogenicity of the *P. aeruginosa* OMP vaccine in human, and at the same time to determine an optimal dose for human use. The results of the study indicated that the *P. aeruginosa* vaccine is well tolerated and highly immunogenic in healthy humans and that 0.5 or 1.0 mg is the optimal dose for human use.

In an effort to evaluate the protective efficacy of the *P. aeruginosa* OMP vaccine in patients at a high risk of *P. aeruginosa* infection, we carried out Phase II clinical trials on burn patients. We strongly suggest that anti-*P. aeruginosa* OMPs antibodies elicited in burn patients by active immunization are specific to the OMPs and capable of conferring protection against infection with *P. aeruginosa*. Based on the clinical data, we demonstrated that the optimal immunization schedule for human use is the intramuscular administration with 1.0mg doses of the vaccine by the three times at 7-day intervals. In conclusion, the results of our clinical studies warrant further development of the vaccine for prevention against *P. aeruginosa* infection in burn patients.