

A Hepatitis B vaccine with a novel adjuvant SBP (HBsAg-binding protein)

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In general, adjuvants play a very important role in vaccine. SBP is a HBsAg-binding protein which is screened out from human liver cDNA expression library. SBP has been confirmed to promote dendritic cells (DC) to phagocytize HBsAg more effectively and enhance the immunogenicity. These results suggest that SBP could be developed into a safe and promising adjuvant of Hepatitis B vaccine. In this study, the secretory SBP recombinant *Pichia pastoris* strain is cultured and fermented, then SBP is purified from fermentation supernatant. The proportion of SBP in hepatitis B vaccine (*Hansenula Polymorpha*) is studied, finally a hepatitis B vaccine with the novel adjuvant SBP is manufactured and tested totally according to the requirements. All of the test items are qualified. Its safety, efficacy and stability are evaluated. The efficacy is significantly superior than the control vaccine. The safety and stability are qualified. The results indicate that the novel Hepatitis B vaccine is expected to overcome nonresponsiveness and hyporesponsiveness in a significant number of individuals, and to shorten the hepatitis B vaccine standard 3-dose vaccination regimen to 2-dose regimen, which need to be validated by clinical trials.

Biography:

Engineering Doctor student in Biotechnology & Bio-Pharmacy, State key lab of genetic engineering, College of Life Sciences, Fudan University Shanghai 200433, PR China. Ms. Su has worked in R&D of diagnostic reagents, monoclonal antibodies, cytokines, vaccines and other biological products for over twenty years. She is focused on R&D hepatitis B, E and HPV vaccine in recent years. She led the team to have gotten 5 production licenses and 2 clinical approvals related to recombinant hepatitis B vaccine. Now HEV and HPV vaccines are in preclinical research.