



Development of HBc virus-like-particle as a novel mucosal adjuvant

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Experience:

<https://www.ntuh.gov.tw/Ped/peo/DocLib6/%E9%BB%83%E7%AB%8B%E6%B0%91.aspx>

Market Needs:

The global vaccine adjuvants market is expected to reach USD 769.4 Million by 2021 from USD 467.0 Million in 2016. The major factors driving the growth of this market are high prevalence of infectious and zoonotic diseases, increasing focus on immunization programs by various government bodies, and growing focus on improved and long-lasting immunization against existing and emerging diseases. Vaccines delivered through mucosal surfaces are increasingly studied because of their properties to effectively induce mucosal immune responses, are cheap, easily administrable and suitable for mass vaccinations.

Our Technology:

Using optimal codons for *Escherichia coli* expression, we have constructed, expressed and purified recombinant HBcAg148 protein. Purified HBcAg148 has been confirmed to form virus-like particles by TEM. The efficiency of HBcAg148 in enhancing the immune responses has been studied *in vivo* by dosing mice with our RSV vaccine candidate HR024 together with our adjuvant candidate HBcAg148 intranasally. Humoral immunologic responses against HR024, FIRSV, RSV sites 0, II, and IV as well as protective efficacy of this HR024/HBcAg148 mixture was evaluated. Using this approach, we demonstrated that HBcAg148 could enhance serum total IgG, IgG1 and IgG2a responses against RSV and this adjuvant effect is similar to CpG motif.

Strength:

Because of concerns about adverse effects when giving vaccines to healthy people, The U.S FDA has been conservative about approving new vaccine adjuvants. Our adjuvant candidate, HBcAg148 virus-like particles, are inert, empty capsids, which are formed by the self-assembly of capsid proteins from Hepatitis B virus (HBV). HBV infection affects approximately 2 billion people in the world, and HBV infection of adults is usually transient. HBcAg148 VLPs are non-infectious because they assemble without incorporating genetic material.

Competing Products:

Aluminum gels or aluminum salts are vaccine ingredients that have been used in vaccines since the 1930s. Aluminum is one of the most common metals found in nature. The amount of aluminum present in vaccine is low and is regulated by the U.S FDA. But even though widely used, alum is comparatively weak and will only work with certain diseases.

Monophosphoryl lipid A has been used since 2009 in one vaccine in the US, Cervarix. This immune-boosting substance was isolated from the surface of bacteria.

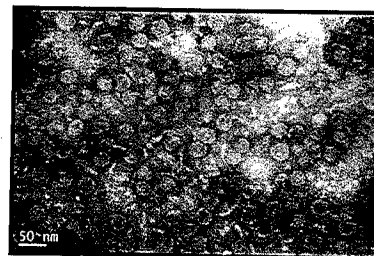
Intellectual Properties:

The technology is not yet submitted for any patent application.

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