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Development of novel therapeutic hepatitis B vaccine

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Despite the existence of effective prophylactic vaccines, hepatitis B virus (HBV) infections remain a major public health problem. About 370 million people are chronically infected worldwide. Chronic hepatitis b (CHB) infection also increases the risk of liver diseases such as cirrhosis and hepatocellular carcinoma. Current antiviral therapies fail to control viral replication in the long term in most patients. As HBV persistence has been associated with a defect in the development of HBV-specific cellular immunity, therapeutic vaccination has been extensively studied in CHB. HBsAg-based vaccines, including prophylactic vaccines and HBsAg-based formulations with novel adjuvants have been used with unclear or negative results. The development of therapeutic vaccines against CHB requires proofing the capacity of the formulation to subvert a tolerated immune response. NASVAC as a new generation vaccine include the use of a novel immunization route (intranasal-IN) and a novel antigen (HBcAg) expressed in E. coli, used in a combined formulation with HBsAg. The evaluation in mouse support the rationality of the therapeutic vaccine candidate targeting the stimulation of CD4(+) and CD8(+) T-cell responses and the induction of pro-inflammatory cytokines capable of controlling viral replication. NASVAC proved to be immunogenic in mouse models and then in phase I, II and III, randomized, double blinded and placebo controlled clinical trials developed in healthy volunteers and CHB patients.

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