Research and development of nasal vaccines against influenza or Covid-19 based on cationic nano-gel delivery system

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In the COVID-19 pandemic, injectable vaccines such as mRNA vaccines, were used around the world about a year after the first infection report. However, pandemic has been still no end now, it is obvious that the spread of infection cannot be controlled by injectable vaccines. Injectable vaccines are not effective for inducing antibodies in the upper respiratory tract (URT) mucosa, which is the entry route of the viruses, and cannot protect against infection.
In this project, targeting seasonal influenza and COVID-19, we'll try to combine antigens with novel nasal vaccine delivery vehicle, cationic nanogel (cCHP) and improve nanogels to optimize most effective compositions. We'll also verify adjuvant addition and develop a cCHP-based nasal vaccine that can protect against infection and suppress transmission by highly induction of neutralizing antibodies in the URT mucosa.

・Exploratory research (2023)

So far, it has been confirmed that antigen-cCHP intranasal vaccines show mucosal IgA induction that cannot be induced by injection in non-human primates. However, the required amount of antigen is large, thus we considered the possibility that there is a problem in the infiltration of the vaccine into the nasal tissue. We'll seek a best composition that improves kinetics by exploring methods for combining nanogels and antigens, selecting antigens, and modifying nanogels. Furthermore, we'll set non-clinical goals based on the correlation between mucosal antibody titers and protection effects in URT. Exploratory research will proceed with two infectious diseases, and determine which to prioritize based on progress in vaccine component selection and setting non-clinical goals.

・Optimization and mechanism research (FY2024)

The goal is to examine the combination of selected vaccines and adjuvants, and determine candidates to proceed to non-clinical trials based on immunogenicity in rodents and primates. In rodents, we'll confirm the protective effect against infection and suppression of transmission and analyze the immune induction mechanism and immune memory.

・Pre-clinical/clinical studies (FY2025-2026)

Conduct GLP safety and immunogenicity studies of the optimaized composition vaccines. Advance clinical development as a cCHP-based nasal vaccine for priority infectious diseases and start Phase 1/2 trials in Japan.

・Expected results

The development of nasal vaccines that induce sufficient mucosal immunity against two

representative respiratory infections and solve the social loss caused by the spread of infection is expected. By accumulating know-how and establishing a supply system through the development of nasal vaccines, it is expected to contribute to swift pandemic control in a new emergency.