NATIONAL CANCER INSTITUTE
Technology Transfer Center

Adjuvanted Mucosal Subunit Vaccines for Preventing SARS-CoV-2 Transmission and Infection

Summary

Investigators at the National Cancer Institute (NCI) have discovered an adjuvanted mucosal subunit vaccine to prevent SARS-CoV-2 transmission and infection. The mucosal vaccine is composed of a novel molecular adjuvant nanoparticle that induces robust humoral and cellular immunity, as well as trained innate immunity with enhanced protection against respiratory SARS-CoV-2 exposure. The technology is available for potential licensing or collaborative research to co-develop these therapeutic targets.

NIH Reference Number

E-064-2021

Product Type

- Therapeutics
- Vaccines

Collaboration Opportunity

This invention is available for licensing and co-development.

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Description of Technology

The Corona virus disease, 2019 (COVID-19) pandemic is a worldwide public health crisis with over 153 million confirmed cases and 3.2 million deaths as of April 2021. COVID-19 is caused by a novel coronavirus called SARS-CoV-2. SARS-COV-2 infects hosts via its spike (S) protein, which has two portions, S1 that binds the cell and S2 that is involved in viral entry via fusion with the cell membrane. There are several vaccines available for COVID-19 patients that directly target SARS-CoV-2 by systemic immunization.

Investigators at NCI have designed a unique adjuvanted mucosal subunit vaccine to prevent SARS-CoV-2 transmission and infection. The mucosal vaccine is generated as a subunit vaccine with spike protein S1 used for an intramuscular (IM) primed vaccine

followed by intranasal boosted mucosal vaccine in rhesus macaques. The mucosal vaccines are administered intranasally and adjuvanted with the combination of TLR agonists CpG and Poly I:C and cytokine IL-15 incorporated in PLGA or DOTAP nanoparticles. The IM-alum-only vaccine induced robust binding and neutralizing antibody and persistent cellular immunity systemically and mucosally, while IN boosting with nanoparticles including IL-15 and TLR agonists elicited weaker T-cell and antibody responses, but higher dimeric IgA and IFNa, enhancing the effect of systemic immunization. Studies conducted by the inventors showed that the mucosal vaccine induced robust humoral and cellular as well as trained innate immunity in the vaccinated macaques, and cleared virus from the nasal mucosa more effectively, which should reduce forward transmission.

Overall, the results demonstrated that the mucosal vaccine could protect against respiratory SARS-CoV-2 exposure and may enhance systemic vaccines, and thus is a good candidate for a SARS-CoV-2 vaccine. Inventors are seeking licensing and/or co-development research collaborations for a unique novel molecular Adjuvanted Mucosal Subunit Vaccine to prevent SARS-CoV-2 transmission and infection.

Potential Commercial Applications

- Adjuvanted mucosal subunit vaccines (as single agents)
- Vaccine composition (s)
- Co-administration to enhance the effect of systemic immunization.

Competitive Advantages

Stimulates both systemic and mucosal immunity; induces both humoral and cellular immunity, as well as trained innate immunity
Leads to more effective virus clearance from the upper respiratory tract from which it could spread.
Stimulated sustained immune response
Protects against SARS-CoV-2 variants
Intranasal administration avoids painful injection
Notable improvement for manufacturing yield and cost, ease of administration, and distribution as compared to current candidates.

Inventor(s)

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Development Stage

- Pre-clinical (in vivo)

Publications

Yongjun Sui et al., Protection against SARS-CoV-2 infection by mucosal vaccine in rhesus macaques. [Protection against SARS-CoV-2 infection by a mucosal vaccine in rhesus macaqu...]

Patent Status

- **U.S. Provisional:** U.S. Provisional Patent Application Number 63/146,279 , Filed 05 Feb 2021

Therapeutic Area

- Infectious Diseases
- Immune System and Inflammation

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