National Institute of Allergy and Infectious Diseases

Prickly Patch Delivery of Experimental COVID-19 Vaccine Shows Promise in Animal Study

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A candidate vaccine delivered though a thumbnail-sized patch studded with microneedles could help address the coronavirus disease 2019 (COVID-19) pandemic. NIAID-funded scientists at University of Pittsburgh School of Medicine tested the vaccine delivery device in mice and published the results April 2 in *The Lancet* journal *EBioMedicine*.

Previous research on the coronaviruses that cause severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) by co-lead investigator Andrea Gambotto, M.D., and his colleagues laid the groundwork for the current investigation of the spike (S) protein of the novel coronavirus, SARS-CoV-2, which causes COVID-19. The virus uses the S protein to enter cells and initiate infection. In response, the body eventually develops antibodies directed against SARS-CoV-2, and they help control and end the infection. Vaccination gives the immune system a “preview” of a virus or other disease-causing pathogen so that protective antibodies can be rapidly produced if a vaccinated person later encounters that pathogen. If vaccine-generated antibody and other immune responses are sufficiently robust, infection is prevented.

The experimental Pittsburgh coronavirus vaccine, PittCoVacc, is made from parts of the virus S protein impregnated into 400 tiny needles on a small adhesive patch. Once attached, the microneedles, which are made of sugar, dissolve and deliver the viral protein directly to immune cells in the skin that are especially responsive to viral invaders.

When tested in mice, PittCoVacc generated a surge of antibodies against SARS-CoV-2 within two weeks of the microneedle prick. The vaccinated animals have not yet been tracked long-term, but the researchers note that mice vaccinated with a microneedle patch against MERS-CoV produced sufficient antibody levels to neutralize the virus for at least a year. The antibody levels of the SARS-CoV-2-vaccinated animals are following a similar trend, the team reports.

The SARS-CoV-2 microneedle vaccine maintains its potency after gamma radiation sterilization—a useful feature for the eventual manufacture of product suitable for human use. Additionally, the components of the experimental vaccine can be made rapidly and at large-scale, say the investigators, and the final product does not require refrigeration, which means that vaccine patches could be produced and placed in storage until needed.

The team has begun the process of obtaining approvals from the U.S. Food and Drug Administration in anticipation of launching a Phase 1 trial of the candidate vaccine within the next several months.

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Reference: E Kim *et al*. Microneedle array delivered recombinant coronavirus vaccines: Immunogenicity and rapid translational development (https://www.sciencedirect.com/science/article/pii/S2352396420301183?via%3Dihub) . *EBioMedicine* DOI: 10.1016/j.ebiom.2020.102743. (2020).

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