Single-shot COVID-19 vaccine protects non-human primates

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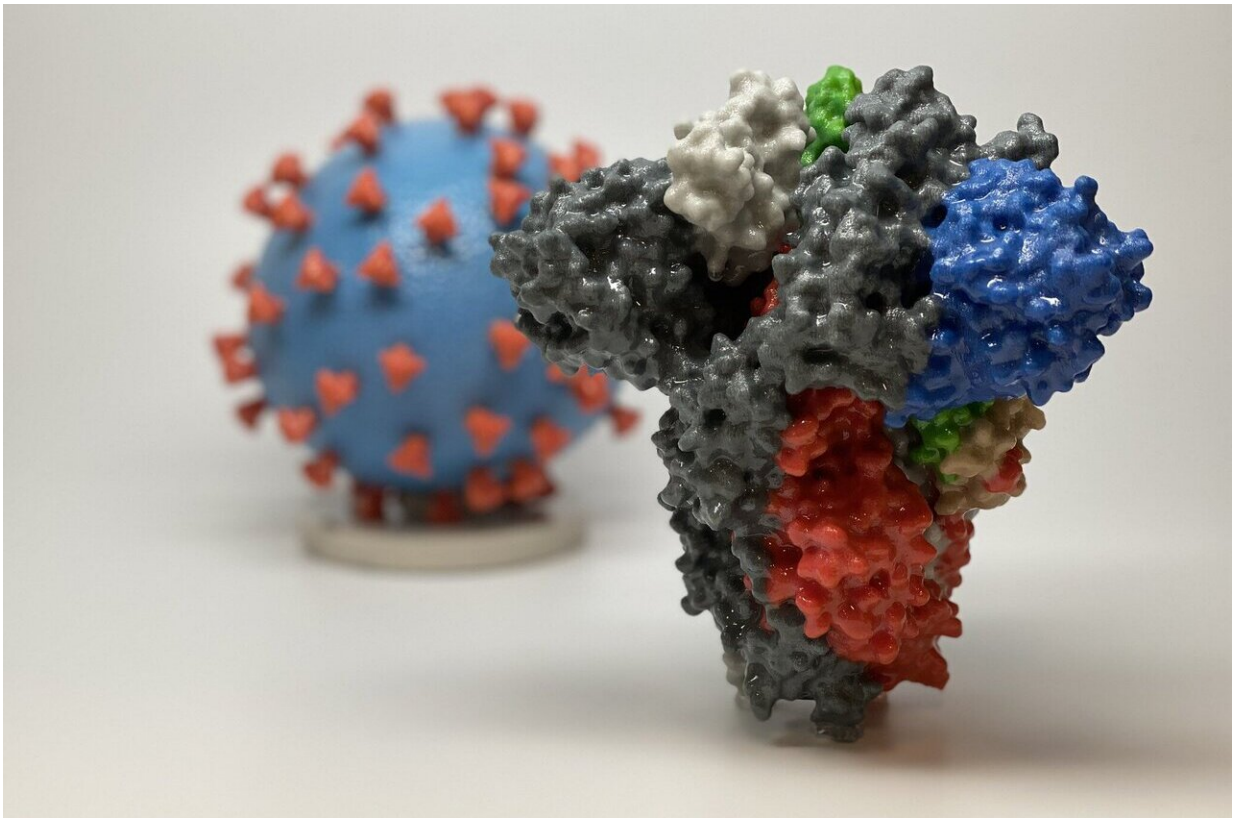

3D print of a spike protein of SARS-CoV-2, the virus that causes COVID-19—in front of a 3D print of a SARS-CoV-2 virus particle. The spike protein (foreground) enables the virus to enter and infect human cells. On the virus model, the virus surface (blue) is covered with spike proteins (red) that enable the virus to enter and infect human cells. Credit: NIH

The development of a safe and effective vaccine will likely be required to end the COVID-19 pandemic. A group of scientists, led by Beth Israel Deaconess Medical Center (BIDMC) immunologist Dan H. Barouch, MD, Ph.D., now report that a leading candidate COVID-19 vaccine developed at BIDMC in collaboration with Johnson & Johnson raised neutralizing antibodies and robustly protected non-human primates (NHPs) against SARS-CoV-2, the virus that causes COVID-19. This study builds on the team's previous results and is published in the journal *Nature*.

"This vaccine led to robust protection against SARS-CoV-2 in rhesus macaques and is now being evaluated in humans," said Barouch, who is Director of BIDMC's Center for Virology and Vaccine Research.

The vaccine uses a common cold virus, called adenovirus serotype 26 (Ad26), to deliver the SARS-CoV-2 spike protein into host cells, where it stimulates the body to raise immune responses against the coronavirus. Barouch has been working on the development of a COVID-19 vaccine since January, when Chinese scientists released the SARS-CoV-2 genome. Barouch's group, in collaboration with Johnson & Johnson, developed a series of vaccine candidates designed to express different variants of the SARS-CoV-2 spike protein, which is the major target for neutralizing antibodies.

Barouch and colleagues conducted a study in 52 NHPs, immunizing 32 adult rhesus macaques with a single dose of one of seven different versions of the Ad26-based vaccine, and giving 20 animals sham vaccines as placebo controls. All vaccinated animals developed neutralizing antibodies following immunization. Six weeks after the immunization, all animals were exposed to SARS-CoV-2. All 20 animals that received the sham vaccine became infected and showed high levels of virus in their lungs and nasal swabs. Of the six animals that received the optimal vaccine candidate, Ad26.COV2.S, none showed virus in

their lungs, and only one animal showed low levels of virus in nasal swabs.

Moreover, neutralizing antibody responses correlated with protection, suggesting that this biomarker will be useful in the clinical development of COVID-19 vaccines for use in humans.

"Our data show that a single immunization with Ad26.COV2.S robustly protected rhesus macaques against SARS-CoV-2 challenge," said Barouch, who is also the William Bosworth Castle Professor of Medicine at Harvard Medical School, a member of the Ragon Institute of MGH, MIT, and Harvard, and a co-leader of the vaccine working group of the Massachusetts Consortium on Pathogen Readiness. "A single-shot immunization has practical and logistical advantages over a two-shot regimen for global deployment and pandemic control, but a two-shot vaccine will likely be more immunogenic, and thus both regimens are being evaluated in clinical trials. We look forward to the results of the clinical trials that will determine the safety and immunogenicity, and ultimately the efficacy, of the Ad26.COV2.S vaccine in humans."

Investigators at Beth Israel Deaconess Medical Center (BIDMC) and other institutions have initiated a first-in-human Phase 1/2 clinical trial of the Ad26.COV2.S vaccine in healthy volunteers. Kathryn E. Stephenson, MD, MPH, is the principal investigator for the trial at BIDMC, which is funded by Janssen Vaccines & Prevention, B.V., a pharmaceutical research arm of Johnson & Johnson.

Pending clinical trial outcomes, the Ad26.COV2.S vaccine is on track to start a phase 3 efficacy trial in 30,000 participants in September.

More information: Noe B. Mercado et al, Single-shot Ad26 vaccine protects against SARS-CoV-2 in rhesus macaques, *Nature* (2020). DOI: 10.1038/s41586-020-2607-z

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