Investigational COVID-19 vaccine well-tolerated, generates immune response in older adults

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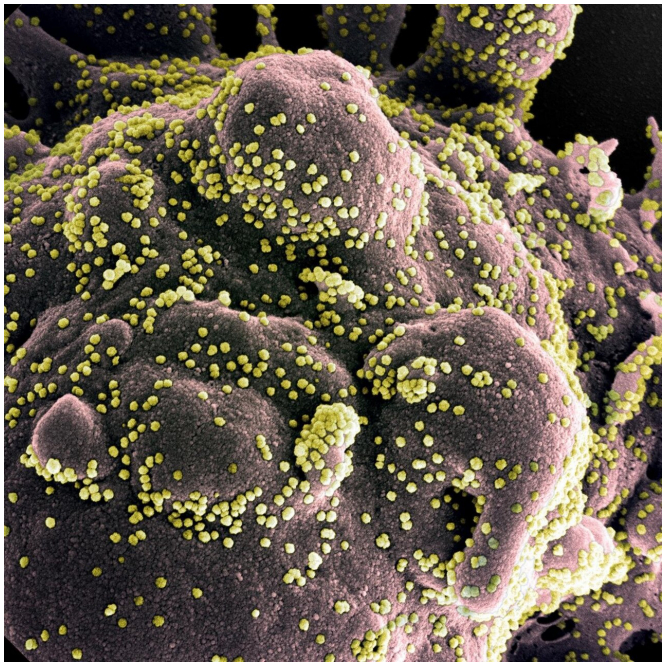

Colorized scanning electron micrograph shows SARS-CoV-2 virus particles (yellow), isolated from a patient. Credit: NIAID

A Phase 1 trial of an investigational mRNA vaccine to prevent SARS-CoV-2 infection has shown that the vaccine is well-tolerated and generates a strong immune response in older adults. A report published today in the *New England Journal of Medicine* describes the findings from the study, which was supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. SARS-CoV-2 is the virus that causes COVID-19 disease.

The experimental vaccine, mRNA-1273, was co-developed by researchers at NIAID and Moderna, Inc. of Cambridge, Massachusetts. The Phase 1 trial began on March 16, 2020, and was expanded to enroll older adults about one month later. Older adults are more vulnerable to complications of COVID-19 and are an important population for vaccination. Understanding how the vaccine affects older adults is a critical part of measuring its safety and efficacy.

The trial was conducted at Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle, Emory University in Atlanta, and NIAID's Vaccine Research Center (VRC) clinic at the NIH Clinical Center in Bethesda, Maryland. Julie Ledgerwood, D.O., deputy director and chief medical officer at the VRC, oversaw the study at the NIH site. The Coalition for Epidemic Preparedness Innovations (CEPI) supported the manufacturing of the vaccine candidate for this trial. This trial is supported by the Infectious Diseases Clinical Research Consortium (IDCRC) through NIAID.

In its expansion to include older adults, the trial enrolled 40 healthy volunteers: 20 adults ages 56 to 70 years, and 20 adults ages 71 years and older. Ten volunteers in each age group received a lower dose of the vaccine (25 ?g), and 10 volunteers in each age group received a higher dose (100 ?g). After approximately one month, volunteers then received a second dose of the same vaccine at the same dosage. Throughout the study, volunteers attended clinic visits to track their responses to the vaccine and assess safety.

Overall, the researchers found that the investigational vaccine was well-tolerated in this older age group. Although some volunteers experienced some transient adverse effects, including fever and fatigue after vaccination, the researchers found that they also exhibited a good immune response to the vaccine: the blood of vaccinated volunteers contained robust binding and

neutralizing antibodies against SARS-CoV-2. Importantly, the immune response to the vaccine seen in older volunteers was comparable to that seen in younger age groups.

The study will continue to follow the older volunteers for approximately a year after second vaccination to monitor the long-term effects of the vaccine. According to the researchers, these Phase 1 trial results further support testing of the investigational vaccine in older adults in an ongoing large Phase 3 trial.

More information: Evan J. Anderson et al, Safety and Immunogenicity of SARS-CoV-2 mRNA-1273 Vaccine in Older Adults, *New England Journal of Medicine* (2020). DOI: 10.1056/NEJMoa2028436

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