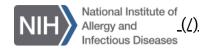
(和ttps://www.coronavirus.gov) (和ttps://www.nih.gov/coronavirus)



NIH Clinical Trial of a Vaccine for COVID-19 Now Enrolling Older Adults

Study sites Located in Seattle, Atlanta and Bethesda

April 17, 2020

Investigators are no longer seeking volunteers ages 18 to 55 for this trial. Adults over the age of 55 in the Atlanta, Bethesda or Seattle areas who are interested in joining this study should contact: Atlanta: vaccine@emory.edu / 404-712-1371 (for the Hope Clinic in Decatur) or ecc.vaccine@emory.edu / 404-727-4044 (for the Emory campus in Atlanta); Bethesda: VRCCOVIDtrials@nih.gov; Seattle (age 71 and older only): kpwa.vaccine@kp.org.

3D print of a spike protein on the surface of SARS-CoV-2—also known as 2019-nCoV, the virus that causes COVID-19. Spike proteins cover the surface of SARS-CoV-2 and enable the virus to enter and infect human cells. For more information, visit the NIH 3D Print Exchange at 3dprint.nih.gov.

Credit: NIH

A Phase 1 clinical trial of an investigational vaccine designed to prevent coronavirus disease 2019 (COVID-19) is now enrolling older adults. The trial began on March 16, 2020 and was originally designed to enroll 45 healthy volunteers ages 18 to 55 years. Enrollment of the first 45 participants is now complete, and investigators have expanded the trial to enroll an additional 60 participants: 30 adults ages 56 to 70 years and 30 adults ages 71 years and older. The trial is supported by the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health.

Enrolling older adult volunteers in the trial will help investigators better understand vaccination safety and immune response among older people, who face a higher risk of complications from COVID-19 than younger individuals. Study investigators have conducted regular safety reviews and have not identified any significant safety issues among younger volunteers. Regular safety reviews will continue as older adults are enrolled.

The clinical trial is evaluating different doses of the investigational vaccine for safety and its ability to induce an immune response in participants. It has been underway at Kaiser Permanente Washington Health Research Institute (KPWHRI) in Seattle and Emory University in Atlanta, both part of NIAID's <u>Infectious Diseases Clinical Research Consortium</u> \square

(https://www.nih.gov/news-events/news-releases/infectious-diseases-clinical-research-consortium-awards-announced)
NIAID's Vaccine Research Center (VRC) clinic at the NIH Clinical Center in Bethesda, Maryland has been added as a trial site.
Julie Ledgerwood, D.O., deputy director and chief medical officer at the VRC will oversee the study at the NIH site.

All three sites will enroll older adults in the coming weeks. Participants will receive two shots of the experimental vaccine approximately one month apart and will be followed for approximately one year. The vaccine, called mRNA-1273, was developed by VRC scientists and the biotechnology company Moderna, Inc. The Coalition for Epidemic Preparedness Innovations (CEPI) supported the manufacturing of the vaccine candidate for the Phase 1 clinical trial.

Trial data will be disseminated to public health officials and partners as soon as possible and included in scientific publications and presentations to inform the global scientific community.

For more details on the trial, please see NIAID's March 16 press release (https://www.niaid.nih.gov/news-events/nih-clinical-trial-investigational-vaccine-covid-19-begins), NIAID's March 27 statement (https://www.niaid.nih.gov/news-events/atlanta-site-added-nih-clinical-trial-vaccine-covid-19), and visit ClinicalTrials.gov and search identifier NCT04283461 (https://clinicaltrials.gov/ct2/show/NCT04283461) . Investigators are no longer seeking volunteers ages 18 to 55 for this trial. Adults over the age of 55 in the Atlanta, Bethesda or Seattle areas who are interested in joining this study should contact:

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Bethesda:

VRCCOVIDtrials@nih.gov

Seattle (age 71 and older):

kpwa.vaccine@kp.org

Contact

To schedule interviews, contact NIAID Office of Communications (301) 402-1663

NIAIDNews@niaid.nih.gov (mailto:)

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