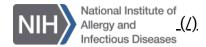
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Developing Therapeutics and Vaccines for Coronaviruses

NIAID-funded scientists are exploring ways to treat and prevent human coronavirus infections by working to develop new antibodies, drugs, and vaccines. Some block the virus from entering cells, some delay the immune system response, and some block viral replication. For COVID-19, NIAID scientists, working in Bethesda, Md., and Hamilton, Mont., are testing the antiviral drug remdesivir. NIAID is supporting a randomized, controlled clinical trial to evaluate the safety and efficacy of remdesivir in hospitalized adults diagnosed with COVID-19 (https://www.niaid.nih.gov/news-events/nih-clinical-trial-remdesivir-treat-covid-19-begins). The trial can be adapted to evaluate additional investigative treatments. NIAID also is exploring other broad-spectrum antiviral compounds for activity against COVID-19 and plans to evaluate the HIV medication Kaletra, also known as lopinavir and ritonavir, and interferon-beta for their activity against, SARS-CoV-2, the virus that causes COVID-19.

The NIAID <u>Vaccine Research Center (https://www.niaid.nih.gov/about/vrc)</u> (VRC) is drawing on broad research experience with coronaviruses and collaborators from academia, other government agencies and industry to develop a vaccine candidate. They collaborated with the biotechnology company Moderna, Inc., to develop an investigational messenger RNA (mRNA) vaccine designed to prevent MERS, but quickly adapted for COVID-19. A <u>Phase 1 clinical trial of the vaccine</u> (https://clinicaltrials.gov/ct2/show/NCT04283461?cond=covid-19&cntry=US&draw=2&rank=2#_blank is being held at the Kaiser Permanente Washington Health Research Institute in Seattle, Emory University in Atlanta and the NIH Clinical Center in Bethesda, Maryland (https://www.niaid.nih.gov/news-events/nih-clinical-trial-vaccine-covid-19-now-enrolling-older-adults). In a Phase 1 clinical trial, a vaccine is given to healthy volunteers to test if it is safe and induces an immune response. Clinical testing to establish a vaccine's safety and efficacy—which can include a Phase 2, Phase 2b and Phase 3 clinical trial—takes time. It is important to note that a COVID-19 vaccine likely will not be widely available to the public until sometime in 2021.

NIAID scientists at Rocky Mountain Laboratories are collaborating with Oxford University investigators on the development of a chimpanzee adenovirus-vectored vaccine candidate against COVID-19 (COVID-19 (COVID-19 (COVID-19 (<a href="https://www.niaid.nih.gov/news-events/investigational-chimp-adenovirus-mers-cov-vaccine-protects-monkeys). In addition, NIAID-supported scientists also are working to see if vaccine candidates developed for SARS are effective against COVID-19.

Grantees studying MERS are working to develop vaccines that target the viral Spike protein of a live, attenuated MERS vaccine, which is a type of vaccine that contains a version of the living microbe that has been weakened in the lab so it cannot cause disease. Grantees and NIAID VRC investigators are using knowledge learned from SARS vaccine development to create MERS treatments. One method for MERS uses neutralizing monoclonal antibodies—developed from a recovered MERS patient and immunized rhesus macaques—that target multiple sites on the virus S protein.

NIAID has also supported the clinical testing of two promising antibody-based therapeutics, which prevent the virus from infecting and entering cells. NIAID conducted a Phase 1 clinical trial of SAB-301 (Phase-1-trial), an experimental MERS treatment developed from cattle that make human antibodies. This was shown to be safe and well tolerated in healthy adults. More recently, NIAID supported a Phase 1 clinical trial of a combination of two monoclonal antibodies, Phase 1 clinical trial of a combination of two monoclonal antibodies, Phase 1 clinical trial of a combination of two monoclonal antibodies, Phase 1 clinical trial of a combination of two monoclonal antibodies, Phase 2 https://www.niaid.nih.gov/news-events/experimental-mers-treatments-enter-clinical-trial), and demonstrated this combination was also safe and well tolerated. Planning for follow on Phase 2/3 efficacy studies using SAB-301 is currently ongoing with partners where MERS is endemic, including the Kingdom of Saudi Arabia.

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