

Promising results mean coronavirus vaccine trial could start by August

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(HealthDay)—Animal studies of a potential COVID-19 vaccine have

been so encouraging that researchers plan to speed up testing of the vaccine in humans.

Initially, the next phase of the trial was expected to begin in September, but that start date has now been moved to August.

Developed by researchers at the Duke-NUS Medical School in Singapore, the [vaccine](#) uses [genetic material](#) called messenger RNA to trigger an [immune response](#) in the body. Once injected, the vaccine prompts the body to make proteins like those of the actual virus. The body will then know what coronavirus-infected cells look like and can learn to fight them off.

Most vaccines are purely preventive, but this vaccine may also be able to treat an active case of coronavirus, the scientists added.

The vaccine activates "two arms of the immune system," explained study author Dr. Eng Eong Ooi, deputy director of the Emerging Infectious Diseases Program at Duke-NUS Medical School in Singapore.

One "arm," Ooi explained, prevents a coronavirus infection by teaching the body to recognize the virus. The other kills off infected cells, preventing the illness from spreading within the body.

"In preclinical studies, that's come true—that we can develop both arms of the immune response against coronavirus," Ooi said during a Wednesday media briefing on the vaccine.

Ooi was joined by Thomas Denny, chief operating officer of the Duke Human Vaccine Institute, and David Ridley, faculty director of the health sector management program at Duke's Fuqua School of Business, to discuss the challenges ahead in the race to produce a safe and effective coronavirus vaccine.

Researchers around the world are developing more than 140 vaccines against the coronavirus, according to *The New York Times'* vaccine tracker. There are currently 18 potential vaccines being tested for safety and correct dosing in Phase 1 or 2 [clinical trials](#), and three vaccines are in Phase 3 trials, where they are undergoing large-scale testing.

The Duke team emphasized that any expectation for a vaccine by the end of this year is overly optimistic.

"I think it's entirely possible that a vaccine will be approved this year, but not at scale," Ridley explained. "We might have some people vaccinated this year, but the average person won't be vaccinated."

Denny added, "We may have some good science by the end of the year and think we have some leading candidates. But manufacturing them to have it all administered, that's a tall order to be ready by the beginning of 2021."

There are currently no RNA vaccines on the market for any disease, the researchers said, but many are being tested in clinical trials, both for coronavirus and other diseases.

Most coronavirus vaccines being studied require two doses—including Moderna's RNA vaccine—but Ooi said the vaccine being developed by Duke-NUS and the pharmaceutical company Arcturus Therapeutics is different. So far, it appears this vaccine requires only one dose because it has a replicating effect that makes the vaccine "expand in the body," Ooi explained.

The vaccine will likely be the first of its kind to get this far in clinical trials if the trials proceed as expected.

Although there is some level of uncertainty with a unique vaccine like

this one, the research thus far has demonstrated that the vaccine is safe.

"We are quite confident that given the kind of safety profile we observe with using RNA to deliver drugs, we should be able to get a fairly decent safety profile," Ooi said. "I would think this vaccine will be tolerable and acceptable to the public."

There are several steps and many months of testing ahead for this vaccine.

If the next phase of the trial begins in August, the vaccine will initially be tested on a small group of healthy adults. If it is shown to be safe, it may be tested on more [vulnerable populations](#), such as the elderly. This phase is "quite standard," according to Ooi.

The following step, though, is less certain. In the next phase, a large population would be given either the vaccine or a placebo, and then studied to see if they are infected with the virus naturally. But the speed and efficacy of that stage depend on how common [coronavirus](#) infections are at that time, Ooi explained.

"We can vaccinate the individuals and then see whether that would protect them from COVID, compared to a group where they got the placebo instead," Ooi said. "But, if for whatever reason the disease incidence or prevalence of disease goes down, then it'll take us a much longer time to assess efficacy."

Even if the [trials](#) go according to plan, it is difficult to say when the vaccine could become available for general use. Ooi predicted this time next year "at the soonest."

The research and development of the vaccine is being funded, in part, by the government of Singapore.

More information: The U.S. Centers for Disease Control and Prevention has more on [COVID-19](#).

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