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Local clinical trials soon for two vaccines targeting 4 variants

They will evaluate vaccines' safety and immune response against the variants

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A volunteer (right) meeting SingHealth Investigational Medicine Unit's Associate Professor Jenny Low (left) as part of an early-stage clinical trial for a Covid-19 vaccine in August last year. The unit will be administering the clinical trials for two Covid-19 vaccines targeting four variants of concern. ST FILE PHOTO

Local clinical trials will soon commence for two Covid-19 vaccines, developed by a United States-based company to target four variants of concern, including the Delta variant.

The early-stage clinical trial, which has just received approval from the Health Sciences Authority, will evaluate the vaccines' safety and immune response against the Alpha, Beta, Gamma and Delta variants, and as possible booster shots for vaccinated people. The vaccines were developed by pharmaceutical firm Arcturus Therapeutics.

The trial is looking to recruit healthy volunteers, both male and female, who are between 21 and 65 years old.

It will be administered by SingHealth's Investigational Medicine Unit, which is led by Associate Professor Jenny Low.

Prof Low, the unit's deputy clinical and scientific director, told The Straits Times: "The two new vaccines, ARCT-154 and ARCT-165, will be tested together with the original ARCT-021 vaccine, where we will compare all three vaccines against one another for their safety and antibody protection."

The ARCT-021 vaccine, which was previously known as the Lunar-Cov19 vaccine, is still undergoing phase two of its clinical trials, which began earlier this year. It was co-developed by Duke-NUS and Arcturus Therapeutics, and targets the original or wild-type Sars-CoV-2 virus.

The ARCT-154 vaccine targets the D614G spike protein mutation that has become dominant globally, whereas the ARCT-165 vaccine targets a wider range of viral mutations, Prof Low noted.

A new variant can result from mutations at more than one part of the virus, although the majority of current circulating variants have the D614G mutation.

Some current messenger ribonucleic acid (mRNA) vaccines have lower effectiveness in protecting against symptomatic disease when it comes to targeting certain variants.

Prof Low said a booster jab may be needed for these vaccines in future as the virus will continue to circulate.

The trial is known here as the phase one/two trial.

The phase one trial tests for the vaccines' safety, to ensure that there are no severe side effects. The immune response of the participants will also be measured, said Prof Low.

A total of 72 participants will be recruited – 36 who have yet to be vaccinated, and another 36 who have received the second dose of their Pfizer jab at least six months ago.

Participants will be given any of the three vaccines, which will be administered in two doses, one month apart. Those who have been vaccinated will receive one dose of either vaccine, said Prof Low.

Once the safety of the vaccines have been ascertained, the trial will then move on to phase two, which will involve a larger cohort of volunteers – usually a few hundred – with a focus on the participants' immune response.

This involves measuring the number of neutralising antibodies and T-cells, to ensure that the vaccine can confer long-lasting immunity to the virus and its variants.

Phase three of the trial – which would involve thousands of volunteers – can then conclusively determine the vaccines' efficacy against the four variants, she added.

Arcturus Therapeutics said in a statement last Tuesday that preclinical data have demonstrated that the ARCT-154 and ARCT-165 vaccines are able to induce strong neutralising immunogenicity, or immune response, in non-human primates to the four variants.

All three phases of the clinical trial for the ARCT-154 vaccine have also been approved in Vietnam.

Screening of volunteers for phase one of the trial has already commenced.

Those with chronic conditions, such as high blood pressure or diabetes, must have their conditions stable and well-controlled.

In addition, the volunteers must not have any history of anaphylaxis (a serious form of allergic reactions) to the vaccines, and should have no known history of Covid-19. They must not have participated in any previous Mers-CoV, Sars-CoV and Sars-CoV-2 trials.

Those interested in participating in the trial can contact the SingHealth Investigational Medicine Unit at imu@singhealth.com.sg or call 6323-7544/8318-0685.

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