

First vaccinations next week for clinical trial in Singapore

Volunteers being screened for Lunar-Cov19's early-stage clinical trial that is set to last till Oct

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The early-stage clinical trial for a Covid-19 vaccine has started in Singapore, with the first vaccinations expected to be given to volunteers next week.

Clinicians and researchers are now screening those who have stepped forward to ensure they are suitable for the trial, which is expected to last until October.

The SingHealth Investigational Medicine Unit is administering the trial for the vaccine.

Called Lunar-Cov19, the vaccine is developed by Duke-NUS Medical School and United States pharmaceutical company

Arcturus Therapeutics.

Associate Professor Jenny Low, deputy clinical and scientific director at the SingHealth unit, told *The Straits Times* yesterday that more than 250 volunteers have stepped forward for the trial.

Around 100 people will take part in the trial. The volunteers are in their 20s to 50s.

"As the trial is open to volunteers from 21 to 80 years old, we continue to be on the lookout for more participants, especially those in the older age group," she added.

Prof Low said the volunteer response for the vaccine trial has been encouraging.

"It shows that people are willing to contribute towards the advancement of science, even if the trial

may not benefit them directly."

A vaccine works by "showing" the immune system an important part of the virus and "training" it to recognise and remember a pathogen without exposing the patient to the risk of disease.

Traditional vaccines do this by injecting a killed or weakened form of the virus into the human body so that the immune system recognises the invader and begins summoning its "soldiers" – antibodies and T-cells – to get rid of it.

However, the Lunar-Cov19 vaccine involves a newer type of biotechnology.

The vaccine contains only fragments of the virus' genetic material, instead of the whole virus.

When these viral genetic fragments enter the human cell after injection, the genome fragments commandeer the cell to begin producing the signature spike protein of the coronavirus.

This trains the body to recognise a key part of the virus – the spike protein – without exposing it to the whole virus.

Prof Low said the vaccine had shown promising pre-clinical results, and the next step would be to ensure it is safe, and that it can elicit a robust antibody and T-cell immunity in vaccinated individuals to confer long-lasting protection against Covid-19.

The early-stage clinical trial for the Lunar-Cov19 being conducted here is known in medical circles as a phase I/II trial.

Typically, a phase I vaccine trial involves a small number of subjects, usually fewer than 100.

They are recruited to evaluate the different doses of a vaccine for potential toxicity, and to understand how drugs are removed from the body. The body's immune response will also be measured.

The focus of phase II is similar, ex-

cept the number of subjects is usually increased to several hundreds.

Prof Low said that combining phases I and II for this trial will allow for greater flexibility and help to speed up the trial without any gaps in time after phase I.

She added: "This is important during a pandemic such as Covid-19, where the search for a vaccine is critical to saving lives and should be accelerated where possible without compromising on safety."

Before a clinical trial is allowed to take place, many measures have to be in place to ensure the safety of a vaccine.

This includes having experts conduct extensive pre-clinical tests, such as laboratory tests, animal studies and safety tests.

A vaccine can move into the clinical trial stage only when promising pre-clinical results are shown, Prof Low said.

The trials are also tightly regulated by both ethics and regulatory boards, and close safety monitoring takes place at every phase.

The Lunar-Cov19 vaccine is one of 26 vaccine candidates worldwide that either have been tested on humans or have received approval to do so.

Some 139 others are still at a pre-clinical phase.

"As one of the vaccine candidates in the world that has reached the clinical evaluation stage, this trial is

definitely significant for Singapore," said Prof Low, who is also a senior consultant at the department of infectious diseases at the Singapore General Hospital.

"If the vaccine is efficacious, Singapore would have played a key role in the global search for a Covid-19 vaccine, and hopefully be able to help find a solution to the current pandemic."

Singapore will also have priority access to the vaccine for its population, Prof Low added.

The next phase of the trial – phase III – will look into finding out if the vaccine reduces the occurrence of a particular disease.

ST had earlier reported that phase III of the clinical development process involves inoculating a much larger pool of thousands of volunteers in Singapore and abroad, and that this could start before the end of the year.

Those interested in taking part 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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SCAN TO WATCH
Singapore's human trials for Covid-19 vaccine.
<https://str.sg/vacc>



Race for a vaccine

The early-stage clinical trial for a Covid-19 vaccine, developed by scientists from Duke-NUS Medical School and Arcturus Therapeutics, has started in Singapore, with the screening of volunteers. SingHealth's Investigational Medicine Unit is administering the trial, which is expected to last until October. SingHealth's Associate Professor Jenny Low takes *The Straits Times* on a walkthrough of the process ahead of the first vaccinations, which are expected to start next week.



VOLUNTEERS

- About 100 people aged between 21 and 80 years. During pre-screening, they are asked to provide details such as their age, height and weight, as well as medical history.
- Those selected are briefed about what is expected of them and the potential side effects.
- Volunteers are compensated for their time and inconvenience. If they agree to proceed, they sign a consent form.

SCREENING



- Volunteers go for more detailed medical screening, involving procedures that patients usually undergo during medical check-ups, such as an electrocardiogram of heart activity, and giving blood and urine samples for testing.
- Subjects must be healthy, with no underlying medical conditions.

DOSING

- Before the vaccination is given, volunteers undergo another round of basic health checks.
- After the injection is given in the arm, they are monitored for about four hours at the SingHealth Investigational Medicine Unit (IMU) at the Singapore General Hospital, before being discharged.
- They must record any changes or side effects, and monitor the severity of any symptoms, such as headaches or muscle aches, on a three-point scale of mild, moderate or severe.
- The principal investigator and coordinator is on call 24 hours a day, in case symptoms become severe.



FOLLOW-UP

- Volunteers report to the SingHealth IMU on specific days over the next few months, so that blood samples can be drawn.

Three key aims of the trial:

- Assess the vaccine's safety, such as if there are any severe side effects.
- Determine the appropriate dosage.
- Study whether the immune system mounts a protective response against the virus by generating antibodies and T-cells.

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

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