Frequently Asked Questions

1. What is a vaccine?

A vaccine is a product designed to protect against infectious diseases by stimulating the body's immune system safely.

2. How do vaccines work?

Vaccines stimulate the body's protective immune responses. If a person is infected with a germ, the immune system can quickly prevent the infection from spreading within the body and causing disease. In this way, vaccines mimic natural infection but without actually causing the person to become sick.

3. What is the purpose of this study?

This study tests the safety and effectiveness of the COVID-19 vaccine in the children / adolescent population (between 3 and 11 years old) in a controlled manner before the vaccine is used more widely worldwide.

4. What is the COVID-19 vaccine used in this study?

This is an inactivated vaccine against the virus that causes COVID-19. The Sinovac Life Science company in China develops it.

5. How is this vaccine produced?

The whole virus is killed with a chemical process to no longer multiply and cause disease. This inactivated virus is then used to make the vaccine. The same approach has been used to make the vaccines for flu, polio and hepatitis**.**

6. Is this vaccine halal?

The vaccine is certified halal by the Indonesian Council of Ulama (LPPOM MUI) (Certificate number ID00410000194221020) which JAKIM recognises as a foreign halal certification authority.

7. If I or my child take part in this study, will we definitely get the vaccine?

No, there is a chance that you or your child will get a "placebo" product that does not have any vaccine in it. Each volunteer has an equal chance of receiving the vaccine or the placebo. Half of the volunteers (50%) will receive the vaccine, and half will receive a placebo. With this, we can compare the number of people who get COVID-19 infections by comparing those who got the vaccine and those who did not. Suppose the study vaccine has been shown to be safe and effective. In that case, the volunteers who received the placebo in this study will be offered the study vaccine at no cost at Visit 6 after the approval from Data and Safety Monitoring Board (DSMB).

8. Will one know if we get the vaccine or a placebo?

No, you won't. Neither you nor the study team members know whether you received the vaccine or the placebo. We will keep this as such till the end of the study. We need to do this, so that study findings are accurate and to avoid bias.

9. What are the possible benefits participating in this study?

You or your child may not directly benefit from this study if you or your child receive the placebo (a product that does not have any vaccine in it). However, the information learned from this study could potentially help millions of children to protect themselves and their families from COVID-19 infection. If you or your child received the vaccine, the possible benefit is immunity towards the COVID-19 disease.

10. Is this vaccine safe?

From previous studies, this vaccine can cause common reactions such as pain, swelling, redness and itching at the injection site, and/or fatigue, fever, diarrhoea or other side effects. However, they are usually temporary and mild. The long-term safety profile of the vaccine is unknown, and this study tries to study the vaccine safety profile for up to one year.

11. Can one get COVID-19 infection from the vaccine?

No, it is not possible to get a COVID-19 infection from the vaccine. This vaccine contains inactivated viral particles, which cannot cause any disease. However, some people in the study may test positive for COVID-19 infection from being out in the community or from other sources, not from the vaccine itself.

12. If I or my child had COVID-19 infection in the past, can we still volunteer for this study?

You or your child cannot take part in this study if you or your child had the COVID-19 infection previously.

13. Does a person have to be tested positive for COVID-19 to take part in the study?

No. In this study, we wish to find out if the vaccine can prevent a person from getting COVID-19 infection. It must be tested in volunteers who do not have past COVID-19 infection.

14. How will the vaccine be given?

You or your child will get a vaccine injection in the arm.

15. How many vaccine doses will one gets?

For this study, one will receive two doses of the vaccine or placebo (study product that does not have any vaccine in it) on Day 0 and Day 28, respectively.

16. Do I or my child need to continue wearing a face mask and practice Standard Operating Procedure after receiving the vaccine?

Yes. No one know if you or your child receive the study vaccine or placebo. Ministry of Health Malaysia recommends that during the pandemic, people wear a mask that covers their nose and mouth and practice the SOP when in contact with others outside of their house, when in healthcare facilities, and public places.

17. Do I have to pay for the vaccine in this study?

You do not need to pay for the vaccine or any other study procedures/materials when taking part in this study.

18. Will I or my child get paid if we take part in this study?

We will compensate you for your transportation cost. We will explain the details about compensation when you go through the informed consent process to join the study.

19. Do I or my child have to join the study?

No. You and your child can say yes or no when asked to join any study. All study volunteers must go through a process called “informed consent”. It makes sure volunteers understand the following about the study.

- What will happen in the study
- The risks and benefits of being in the study
- Any alternatives to being in the study
- Participation is voluntary. You or your child may stop being in the study at any time without losing any of your rights or benefits or being penalised in any way
- How will the privacy be protected if one join the study
- Payment and medical treatment options if one is injured by the study
- Who to contact for questions and concerns about the study

20. How is the safety of those who participate protected?

This study complies with the principles of the Declaration of Helsinki and conforms to medical ethics. This study has been reviewed and approved by the Medical Research and Ethics Committee of the Ministry of Health Malaysia to ensure volunteers’ safety and that the benefits of the study outweigh the risks. In the event of any adverse event, the management of the adverse event will be handled by medically qualified personnel(s) accordingly.

21. What will be required of me or my child?

This study involves a series of screening, consent, vaccination and follow up visits. We will first check if you or your child meet the criteria for this study. Suppose you or your child are eligible and agree to participate. In that case, you and your child will need to come to the hospital on the appointed date to receive two doses of the study vaccine or placebo (study product that does not have any vaccine in it) and provide updates to the study team on a regular basis (through phone calls or text messages). We will need to take a throat and nasal swab, urine samples (for women of childbearing ages) and blood samples (for the patient in the immunogenicity subgroup) from you or your child. You are also required to complete the records of Diary Cards (for the patient in the safety subgroup), and inform the study team about any symptoms that you or your child have and any medications you are taking during the study.

22. How long will the study last?

This study will take no longer than 14 months, involving 3 to 7 visits to the hospital and 30 phone calls.

23. How can we get more information about the study?

You can get more information on the study by contacting the general enquiry number through WhatsApp during office hour (Mon-Fri 9am-5pm):

A. Hospital Wanita dan Kanak-Kanak Sabah (6010- 6631055 ; 6012-8250059)
B. Hospital Miri, Sarawak (6011-63399633 ; 6019- 4600763)
C. Hospital Sibu, Sarawak (6016-8538026)
D. Hospital Raja Permaisuri Bainun, Ipoh (6010-2851058)
E. Hospital Seberang Jaya, Penang (6018-2159670)
F. Hospital Sungai Buloh, Selangor (6010-3652342 ; 6010-3648545)
G. Klinik Kesihatan Cheras Baru, Kuala Lumpur (6012-3550810)
H. University Malaya Medical Centre (UMMC), Kuala Lumpur (6012-2290611)

24. Which are the participating hospitals or clinic?

There are ten participating hospitals or clinic**.**

I. Hospital Wanita dan Kanak-Kanak Sabah

J. Hospital Miri, Sarawak
K. Hospital Sibu, Sarawak
L. Hospital Raja Permaisuri Bainun, Ipoh
M. Hospital Seberang Jaya, Penang
N. Hospital Sungai Buloh, Selangor
O. Klinik Kesihatan Cheras Baru, Kuala Lumpur
P. University Malaya Medical Centre (UMMC), Kuala Lumpur
Q. Hospital Pengajar Universiti Teknologi MARA (UiTM) Puncak Alam
R. Klinik Kesihatan Pandamaran, Selangor

25. How many volunteers are needed?

We are looking for 2,000 healthy volunteers age 3 to 11 years old

26. Can I or my child leave the study after it has begun?

Yes. You and your child can leave the study at any time by contacting the study doctor for further discussion.

27. How will the scientists know if the vaccine is effective?

This study uses a design known as “randomized, double-blinded, placebo-controlled clinical trial”. It means that some volunteers in the study will get the study vaccine, and some will get a placebo (study product that does not have any vaccine in it).

The study vaccine and the placebo will appear identical, so neither the volunteers nor the study doctors will know who receives the study vaccine and who receives the placebo. This is what we meant by ‘blinded’. There is a ‘code book’ to record who received the study vaccine and who received the placebo. This information can be accessed in an emergency to protect the volunteers (for example, symptoms of an allergic reaction).

The study team will compare the numbers of volunteers from the vaccine group who test positive for COVID-19 to the number of volunteers from the placebo group who test positive for COVID-19. If the vaccine is effective, the number of

volunteers from the vaccine group who test positive for COVID-19 will be significantly lower than the number of volunteers from the placebo group who test positive for COVID-19.

28. Why is it important to have a diverse group of volunteers in this study?

We want to make sure the vaccine works for everyone. To do this, we need to make sure that people from all walks of life are included in this study. This will help us make sure that we know the study vaccine is safe and effective for all receiving it.

29. Who will see the information if I or my child participate in this clinical trial?

Any information collected about you or your child during the study will be kept confidential. The records will be identified by the study subject number (in accordance with local law). These records will not include full name or address. These records will be kept in the research centre.

The sponsor and its representatives, clinical research associate, auditor, drug regulatory authorities, health regulatory agencies and independent ethics committees or institutional review committees have the right to review your research data at the research site (or the study doctor's office) to examine clinical procedures and information without compromising the confidentiality of information from you or your child.

By signing the informed consent form, you allow your health information to be processed and used during this study.

30. Can I or my child take other medication during the study?

Before the enrolment, your study doctor will evaluate your suitability to join this study. Inform the study doctor what medication you or your child are currently on and whether these medications can be on hold during the study or continue to be taken.

You should inform the study team doctor if you or your child take any medication during the study period, including traditional medicine and non-drug therapy. If you or your child need to take medication for an emergency situation (e.g., an injury due to a dog bite), you can do so, but please inform your study doctor.

31. Is this COVID-19 vaccine effective against new COVID-19 variants?

The effectiveness of this study vaccine against new COVID-19 variants is unknown. Therefore, this study tries to study the vaccine effectiveness against COVID-19 infection among children age 3 to 11 years old.

32. If death or permanent disabilities due to this COVID vaccine happen, will I or my child be covered by trial insurance?

The relevant parties will investigate all permanent disabilities or death during this study. The sponsor will be responsible if the incident is proven to be due to the study vaccine. Trial insurance can be triggered to provide the necessary compensation to the volunteer.

33. Will I or my child be quarantined after getting the COVID vaccine?

No. You and your child are free to do daily activities as usual but do comply with all the SOPs recommended by the government.

34. Why is this study only conducted on individuals who have never been infected with COVID-19?

Individuals who have been infected and recovered from COVID-19 infection may have already developed immunity towards the virus causing the infection. This study tries to study the vaccine effectiveness against the virus. Having volunteers who have recovered from COVID-19 may affect the results of the vaccine effectiveness in the study.

35. Can more than one family member participate in this study?

Yes. All individuals (age 3 to 11 years old) who pass the screening test are eligible for this study.

36. Are the visit dates flexible, or have to be on the exact date?

We will provide you with the visit schedule with an exact date for follow up visit. The schedule depends on the screening date.

37. What if my child is unable to come on the scheduled day?

The follow-up visit is bound by a certain window period; any date reschedule should not exceed this time frame. However, considering manpower and space constraints, the best decision is to stick to the scheduled date.

38. Can my child join another COVID-19 vaccine trial?

During the study period, you are not permitted to participate in any other covid-19 vaccine-related studies. However, if you want to participate in another study, you must withdraw from the current one, and any adverse effects that arise after the withdrawal will not be covered by the sponsor.

39. Can my child join this study if she/he has known case of eczema / allergic to seafood / allergic to previous KKM vaccine?

If there are multiple allergies – will not recruit.
If the child has a history of anaphylaxis to a single allergen– will not recruit.
If the child has a history of allergy to one of the ingredients in CoronaVac – will not recruit.

40. How should my child's vaccinations/follow-up be continued if we intend to move to another state?

We will not recruit anyone who intends to move to another state in the near future.

41. Will my child be eligible to participate in this study if she/he just got an influenza vaccine?

Because influenza is an inactivated vaccine, there should be at least a 7-day gap between the study vaccine and the influenza vaccine. (14 days gap for the attenuated live vaccine)

42. If AE/AR occurs, do parents have the right to request the study to be unblinded?

The safety of the child is paramount. The decision to unblind will depend on the type and severity of AE/AR. There will be a discussion between the PI and sponsor for the final decision

43. Is this vaccine safe? / What are the most frequent adverse effects that my child may experience? / Is there evidence that this vaccine is safe and effective for children? /Is the dose given safe for children?

From previous studies (phase 1&2), this vaccine can cause common reactions such as pain, swelling, itching at the injection site, fever, diarrhea and other side effects. However, most reactions were mild to moderate in severity and transient.

CoronaVac was well tolerated and safe and induced humoral responses in children and adolescents aged 3–17 years. Neutralising antibody titres induced by the 600SU dose were higher than those of the 300SU dose. The results support the use of 600SU dose with a two-immunisation schedule for further studies in children and adolescents.

Additional info: Safety, tolerability, and immunogenicity of an inactivated SARS-CoV-2 vaccine (CoronaVac) in healthy children and adolescents: a double-blind, randomised, controlled, phase 1/2 clinical trial In China aged 3–17 years. 550 participants (vaccine + Placebo)
Lancet Infect Dis 2021
Published Online June 28, 2021 https://doi.org/10.1016/ S1473-3099(21)00319-4

Injection site pain was the most frequently reported event (73 [13%] of 550 participants), occurring in 71 (16%) of 219 participants in the 300SU group, 35 (16%) of 217 in the 600SU group, and two (2%) in the alum-only group. As of June 12, 2021, only one serious adverse event of pneumonia has been reported in the alum-only group, which was considered unrelated to vaccination.

The seroconversion rates of neutralizing antibody with both doses (300SU and 600SU) were over 96% after two-dose vaccination and the neutralising antibody titres induced by the 600SU dose were higher than those induced by the 300SU dose. Taken together, the 600SU dose of CoronaVac induced higher immune responses compared with 300SU dose.

**The dose used in the protocol is 600SU. The dosage explained in the article is 300SU or 600SU.

44. Will my child need to take the second dose if she or he has any adverse effects after the first? / Will my child be asked to continue for a second dose if she/he is sick or hospitalized at the time?

The investigator will assess the child's condition and determine whether to discontinue/postpone/continue with the second dose. However, even if the study intervention is discontinued, the study's follow-up will continue

45. What is myocarditis, and is there a risk of myocarditis after vaccination?

Myocarditis is inflammation of the heart. It can cause chest pain, trouble breathing, irregular heartbeat and, in some cases, death. Most cases are treatable, and many have been mild. Recently, the CDC received reports of increased cases of myocarditis in people who have received the mRNA vaccines (Moderna and Pfizer). Most of the cases occurred in adolescent and young adult males. They are still investigating to determine if this is related to having received a vaccine or coincidence. In general, myocarditis due to COVID-19 and MIS-C in this age group is much more common than occurrences in those who have been vaccinated. Cases of myocarditis, or inflammation of the heart, have been reported in teens after receipt of the COVID-19 mRNA vaccine. The condition is continuing to be investigated. Here is what we know to date:

To date, about 306 million doses of the COVID-19 vaccines have been given, and about 7.2 million of these have been in teens (12-18 years old). Available

data suggest that the incidence of myocarditis following mRNA vaccines is about 1 per 50,000 vaccine recipients. Of interest, myocarditis also occurs more commonly after either acute COVID-19 or as part of the multisystem inflammatory syndrome of children (MIS-C).

Parents and teens should watch for symptoms that may include chest pain, pressure, heart palpitations, difficulty breathing after exercise or lying down, or excessive sweating. One or more of these symptoms may also be accompanied by tiredness, stomach pain, dizziness, fainting, unexplained swelling, or coughing. If a recently vaccinated teen develops these symptoms or you are unsure, contact the child's doctor or seek more immediate medical assistance if needed.

The CDC will continue to monitor the situation related to myocarditis, but for now, there is not a reason to stop vaccinating kids. The American Heart Association has also released a statement encouraging continued vaccination.

At present there are no reports of myocarditis associated with CoronaVac® vaccine

46. Could this vaccine cause clotting problems like AZ vaccine?
At present there are no reports of clotting problems with CoronaVac® vaccine

47. Can I give my child paracetamol before vaccination?
No. You are not advised to give paracetamol because we would want to detect any fever before vaccination

48. Can my child get other non-COVID vaccines (chickenpox / MMR etc) while taking part in the study? Can my child take part if he /she has not completed the National Immunization Program?
Can, but the study vaccine and the non-COVID vaccine should be given at least 14 days apart. Please inform the study team early so that we can arrange the subsequent of appointments accordingly

49. Is there any food my child should avoid taking after the injection?

There is no food restriction, even if your child is getting the active drug

50. Is it necessary for my child to get a nasal swab?

At baseline, a respiratory tract sample will be collected, which may be a nasopharyngeal swab, a throat swab, or saliva for a rapid SARS-CoV-2 antigen test. Because the child must be COVID 19 negative to participate in the study. [Additional info: respiratory tract sample will be required during the study duration if your child is suspected to have COVID-19.]

51. What happen if government open up vaccination programme for children age 3-11 Years Old in Malaysia?

In the event of changes in Malaysia vaccination policy in children age 3-11 Years old, we will consider to revise protocol to allow crossover (meaning patient in placebo arm to receive Sinovac vaccine) to happen before visit 6.