INFORMED CONSENT FORM

Immunogenicity and safety of heterologous combinations of COVID-19 vaccines available under Emergency Use Authorization in Pakistan: A randomized phase II trial

Funding agency	Coalition of Epidemic preparedness Innovations (CEPI)
Principal Investigator	Dr Farah Naz Qamar Associate Professor, Department of Pediatrics and Child Health
Organization	Aga Khan University Hospital
Trial registration Number	Will be applied after ERC approval
ERC Ref Number	6739
Telephone number	
Name of the Study participant	
Date of signing of form	

Introductions:

Assalam o Alaikum, my name is _____. I am working with the Aga Khan University (AKU) for a research study. We are conducting a trial for COVID 19 vaccines in multiple hospitals and areas in Karachi Lahore and Islamabad. This_____ hospital/area is one of the selected trial sites. We would like to invite you to join this trial. Please read/listen to the information carefully again although, you have been provided with a document earlier to help you decide about participation. You are free to ask questions if anything is not clear to you. You are free to decide about your participation in the trial which will be entirely voluntary. We will also provide you a copy of this signed consent form to keep if you decide to participate.

Purpose of the study:

SARS-CoV-2 or COVID 19 or corona virus infection was declared a global pandemic last year and nations were forced to take serious measures such as lockdowns. This pandemic has been causing massive social, financial, economic and health impacts. Social distancing, frequent hand washing and wearing of masks have been advised to control the spread of the virus. Fortunately, in record short time vaccines are now available to help reduce the spread of the disease. The Drug Regulatory Authority of Pakistan (DRAP) has provided emergency use authorization for some available COVID 19 vaccines.These vaccines are being given as single or two doses of similar vaccine with standard interval between two doses. Vaccine shortages, contraindications to a specific vaccine, changes in product availability or migration may make it challenging to give the same vaccine to an individual for both doses. An approach to be able to use

different combinations of available vaccines in case the same vaccine is not available at the time of second dose will be very useful. This approach will not only help overcome the shortage of available COVID-19 vaccines but may also help in exploring the combinations for better immunity. This study will allow us to understand how good these 11 different proposed combinations of available vaccines are in helping to develop immunity against COVID-19 so that policy decisions can be made. You have been invited to participate in the trial as we need healthy adult volunteers. We are recruiting more than 1680 volunteers from all sites.

Study procedures:

If you agree to participate in this trial, we will randomize you to one of the combinations of the trial vaccines, meaning you will be getting any one of the 11 combinations of vaccines and it will be like a lottery or lucky draw generated by a computer.You may or may not receive similar vaccines in both doses, may or may not get a booster dose and the interval between doses will be different from the current standard practices. You will receive the first dose of the vaccine as soon as you agree to participate and the second dose after about 10 weeks of the first dose and a booster dose (if applicable) after 6 months of the first dose. On the day of the first dose, we will also ask a few questions about your health, your household and your weight and height will also be recorded. A blood sample will also be collected. There will be 11 or 13 visits in 2 years, depending on the arm you get on randomization. We will see you 9-10 times during the first year and 2-3 times in the second year of your participation in the trial. During each visit, a few questions about your health will be asked , and blood samples will be collected.These visits will take around 30 to 40 minutes of your time. We will also call you once a week for a month after each dose and then monthly till the end of trial to find out about your health. Each call will be of maximum 5 minutes.A card will be provided to you containing details of all your visits and reminder calls for appointments will also be made. You will have to keep the card and other trial material safe and available during your visits.

The collected blood samples will be tested for immunogenicity and some will be tested in laboratories abroad means samples will be sent outside of the country for some testing and if you agree leftover samples can be stored for any more tests in future which may or may not be for similar objectives.

Vaccination does not provide full protection against Covid-19 infection and there is a chance that you can contract COVID-19. You will be required to follow all SOPs that have been recommended by the government including wearing a mask, social distancing and washing hands frequently. In case of suspicion of contracting the infection, you will also get tested within a week and you should call study physician and will be required to provide an additional nasal swab for the trial.

We have asked, seen documents provided by you and recorded your responses to our questions about your fitness to get enrolled for this trial, however, if you recall or find any more information, please do share with us. We request you to update us about any related health conditions specially about COVID 19 illness, vaccine or pregnancy immediately.

Discomforts, Risks and benefits:

There is a risk of adverse events associated with all vaccines and there can be some risks associated with vaccine administration and blood collection procedures. These side effects can be pain, redness, itch, swelling, fever, feverishness, chills, joint pains, muscle pains, fatigue, headache, malaise, nausea, vomiting, diarrhea etc. Although in most cases the adverse events are mild and self-limiting but can require medication and/or hospitalization in rare cases. A trained person will administer the vaccine and draw blood samples under strict aseptic techniques to ensure minimum discomfort and reduce the risk of infection. You will be given an emergency 24-hour telephone number to contact the study physician as needed. You will be facilitated, and treatment will be arranged if any adverse events due to trial intervention are observed. No direct benefit to you from this trial can be guaranteed. However, by participating in this trial you will be contributing a lot for the betterment, health and lives of millions of countrymen and people around the world. You will be provided monetary compensation for your time, the inconvenience of getting jabs and providing blood samples.

Voluntary participation, withdrawal, and no coercion:

You are free to choose whether or not to participate or continue participation in this study. There will be no penalty or loss of benefits to which you are otherwise entitled if you choose not to participate or not to continue participation in future for the complete trial duration of two years. If you have received both doses of the vaccine no information about the trial vaccines will be given to you. However, if you withdraw after the first dose this information will be provided to you. If you withdraw from the study, storage of your samples will continue and any data collected before withdrawal will still be used in the analysis.

Confidentiality:

The information provided by you will remain confidential. Unique study numbers will be allotted to all participants which will be used instead of names. Only members of our study team will have access to your responses in files kept in cabinets under lock and key and password protected computers or electronic devices. The data of all the participants may be seen by the Ethics review committees/Institutional Review Boards, and will be published in a peer-reviewed journal and presented at other scientific forums without disclosing your name or identity.

Available Sources of Information

The Institutional Review Boards (IRB) of hospitals and labs have approved this study. IRB is an independent committee that safeguards the welfare and rights of human research participants. If you or your family ever have any questions about the study, or if you think you have any concern related to the study, you can contact the study PI, Dr Farah Qamar or AKU ERC at 021-34864955 or 021-34930051 .

Subject's statement

This study has been explained to me in detail, I have read/listened to this consent form and I have had a chance to ask questions and I have received satisfactory answers. I therefore volunteer to take part in this trial. I also understand that I will receive a copy of the signed consent form for my record.

I agree to participate in this research study. i.e.

I agree to accept and receive 2 or 3 doses of vaccines as per trial randomization and schedule.

I agree to attend follow up calls and visits as required during the trial duration of 2 years.

I agree to provide my blood samples/nasal swab as required during the trial.

I agree to permit the use of my leftover samples for any future research. □ Yes □ No

<table>
<tr><td colspan="2">Name of the participant:</td></tr>
<tr><td colspan="2">Parents name/Husband’s name:</td></tr>
<tr><td rowspan="2">Signature or thumbprint of participant:</td><td>Date</td></tr>
<tr><td>Time</td></tr>
<tr><td colspan="2">WITNESS: Necessary if a thumbprint is required or the participant cannot read or write or an interpreter is used. The witness should be independent of the study staff.</td></tr>
<tr><td colspan="2">Name of witness (applicable in case participant is unable to read) or interpreter (applicable in case participant cannot understand our language):</td></tr>
<tr><td colspan="2">I attest the information in this form was accurately explained and apparently understood by the participant and that informed consent was freely given by the participant.

Signature of the witness/interpreter:</td></tr>
<tr><td colspan="2">Name of the study staff obtaining consent:</td></tr>
<tr><td colspan="2">Signature of the study staff obtaining consent:</td></tr>
<tr><td>STUDY ENROLLMENT ID:</td><td>EN</td><td>Loc</td><td>site</td><td>st</td><td>af</td><td>f</td><td>s.</td><td>n</td><td>o.</td><td></td></tr>
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Note: Routing of copies of the consent form:

1) One copy to be given to patient/family
2) One copy to be kept in the investigator's file/research record
3) Original to be placed in the patient’s record