FAQs - RBDCOV Paediatric Clinical Trials

RBDCOV is a European project that will perform two clinical trials currently based on previous AEMPS (Spanish Agency of Medicines and Medical Products) and EMA (European Medicines Agency's) advisory meetings.

1. What is an open label study?

An open label study is a study in which the participant, the clinician and the researcher know which study medication(s) or vaccine(s) participants are receiving.

2. What is a double-blind study?

A blinded study is the opposite of an open label study and the people involved in the study do not know certain information. In a double-blind study, neither the participants nor the researchers know who will be receiving the actual study medication(s) or vaccine(s) or an alternative (called a placebo) that looks like the actual medication or vaccine, but that contains no active ingredients. This is done to make sure that nobody can accidentally influence the results as they do not know who is receiving what.
By using blinding in a study, scientists try to make sure that the research is fair and that the results are accurate. It helps them know if the study medication(s) or vaccine(s) they are testing is really working or if the results are due to other factors.

3. What are eligibility criteria?

Eligibility criteria are a set of guidelines that clarify who can or cannot take part in a study. They include such characteristics as the participant's age, their vaccination status or general health status.

4. What is an informed consent form/written authorisation?

Informed consent is the process of providing the participant and their parent/legal guardian with key information about a research study. This information should be given to them and their parent/legal guardian before deciding whether or not to accept the offer to take part. If the participant and their parent/legal guardian sign this form, it means that they agree to take part in the study. It also tells them about the possible risks and benefits of the study. It should also let them know that the participant can leave the study at any time.

5. Will participation in the clinical trials be confidential and how will privacy be protected?

Horizon2020
European Union Funding
for Research & Innovation

Participation in the clinical trials will be confidential throughout. Personal data will be anonymised, meaning that it will be substituted by a participant number. Our procedures follow strictly the Spanish laws around privacy and confidentiality.

6. How has this vaccine been developed?

As with all medicines, every vaccine must go through in-depth testing to ensure its quality, safety and efficacy before it can be introduced into a country's vaccine programme. Each vaccine under development must first undergo evaluations to determine the best ingredients. An experimental vaccine is first tested in animals to evaluate its safety and its potential to prevent or weaken the severity of an infection and/or disease; then, if the vaccine generates a defence in animals, it is tested in humans through several different phases of clinical trials. This vaccine has recently been approved by the official European medical regulatory body (European Medicines Agency).

7. What are the ingredients in this vaccine?

BIMERVAX® (HIPRA COVID-19 vaccine) includes an important part of a protein from the surface of the SARS- CoV-2 virus. This protein is harmless and is used by our body to generate a defence against the viruses. It does not contain the whole virus, which means participants cannot get infected by the vaccine. The vaccine also contains an emulsion – called an adjuvant – to increase the capacity to build a defence against the virus. The adjuvant used in this vaccine is an emulsion of oil with water.

8. How much time will a participant spend in the clinic/hospital/ centre?

The first appointment will last about 30-45 minutes. The following appointments are expected to last about 15 minutes each.

9. What will happen during the visits?

During the first in-person visit the clinical team will properly explain to the participant and their parent/legal guardian all the objectives of the study and its associated procedures, and check that they understand what their participation in the trial implies. The participant and their parent/legal guardian will then be asked to sign the informed consent form.

If the participant and their parent/legal guardian choose to sign, the participant's medical record and current medications will be reviewed, a medical examination will be performed and blood samples will be collected. Then the study vaccine will be administered and the participant will be asked to remain at the site for a 15-minute observation period. We will provide the participant and their parent/legal guardian with instructions to fill a vaccine diary card for the following 7 days. During the follow-up visits, more blood samples will be collected and we will discuss any side effects that may have occurred and answer any questions.

10. Why will blood samples be taken?

We need to take some blood samples in order to assess the impact that the vaccine has on the body's defence system and overall health condition.

11. Are there risks involved in participating in the clinical trials?

All trials carry a small degree of risk, and so safeguard measures have been put in place to ensure the participant's safety. These measures will be explained to the participant and their parent/legal guardian at their first visit. However, as part of initial safety testing, around 3,000 adults have already been vaccinated and the level of risk is very low.

12. Is it possible to experience side effects during the clinical trials?

Every medication and vaccine may have side effects. Most frequently reported side effects of this vaccine include sensitivity and pain at the injection site, fatigue/tiredness and headache for less than 72 hours, similar to a mild-moderate flu, without limitation of normal daily life activities. In case of any side effects, you should contact the doctor or clinical team to let them know.

13. What safeguards are there to protect the participant during the clinical research?

We do our best to make sure that participation is as safe as possible. Every participant is monitored when the vaccine is administered and followed up throughout the trial by the clinical team. In the background there is an independent board, called the Data Safety Monitoring Board, who looks out for unexpected events related to participants' safety.

14. Can participation be stopped at any time?

Participation is completely voluntary. Participants are always free to withdraw from the study at any time if they no longer want to participate.

15. What will happen to the participant's medical care if they stop participating in the trial?

If a participant or their parent/legal guardian decides to stop their participation in the trial, then their medical care will go back to the previous care pathway.

16. Will I be compensated for participating in the clinical trial?

There is a compensation for the time used for each visit, and to cover the travel expenses. The compensation will be given to the parent or legal guardian. The investigator team will inform about the amount, method and expected schedule for payments.

17. Will the participant need insurance to cover their participation in the study?

No, this matter has been taken care of by the clinical trial insurance.

18. What happens with the results of the participation after the clinical trials end?

Once a clinical trial or study has ended, the researchers will collect and analyse the data to see what next steps are needed as a result of the findings. Results of the research will be made available to the participant and their parent/legal guardian.

19. Why should you or your child participate?

With your participation, you can contribute to science and help others. It will help us to understand better how our investigational vaccine works in adolescents and children. If successful, we hope that the vaccine will give you a stronger defence system against SARS-CoV-2 infection and/or serious symptoms that COVID-19 may cause.