Title HIPRA's COVID-19 vaccine trial in people with immunocompromising conditions was launched in Turkey

One of the objectives of the RBDCOV project is to test whether the vaccine can reactivate or re-generate a protective immune response to SARS-CoV-2 in immunocompetent and immunosuppressed individuals

Accordingly, within the RBDCOV project a clinical trial in Turkey for HIPRA's COVID-19 vaccine in people with immunocompromising conditions started after approval by the Turkish Medicines and Medical Devices Agency on October 28, 2022. This clinical trial will determine whether an additional dose of HIPRA's COVID-19 vaccine can generate an immune response in people living with immune system disorders or who are receiving immunosuppressive treatments.

This study will whether HIPRA's vaccine is able to reactivate or re-generate a sufficient immune response and increase the activity of the immune system (natural defences) to SARS-CoV-2. Additionally, the safety of this new vaccine will be assessed, and it will be studied whether it can prolong the effect of earlier vaccination that the participants have already received.

The Turkish Clinical Study
The clinical trial will involve 60 volunteers from three hospitals in Turkey: two in Ankara (Ankara University Medical Faculty Hospitals and Hacettepe University Medical Faculty Hospitals) and one in Istanbul (Koç University Hospital).

All the volunteers are adults affected by different pathologies or immunosuppressive conditions whose immune system may be less responsive to vaccines. Study participants will include individuals who have received a kidney transplant or have chronic kidney disease, on a dialysis programme.

This clinical trial, led by HIPRA, is carried out in the framework of the European-funded RBDCOV project, which also includes clinical studies with children and adolescents.

Details on the HIPRA COVID-19 Vaccine
The COVID-19 vaccine developed by HIPRA is a bivalent, adjuvanted recombinant protein vaccine based on a receptor-binding domain (RBD) fusion heterodimer comprising the B.1.351 (beta) and B.1.1.7 (Alpha) variants of SARS-CoV-2.

The goal of HIPRA's vaccine is to achieve immunological memory against the SARS-CoV-2 virus. It contains two versions of a fraction of the Spike protein which have been produced in the laboratory: one version corresponds to the RBD of the beta variant spike protein and the other to the RBD of the alpha variant spike protein The Spike protein is found on the surface of SARS-CoV-2 and is used by the

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virus to enter the cells in the body. The vaccine also contains an adjuvant, a solution to increase the capacity to induce an immune response.

When a person is given the vaccine, their immune system identifies the two vaccine RBD proteins as foreign and produces natural defences (antibodies and T-cells) against them. If the vaccinated person later encounters SARS-CoV-2, their immune system will recognise the herringbone protein of the virus and be prepared to attack the virus. Antibodies and immune cells can protect against COVID-19 by working together to kill the virus and prevent it from entering the body's cells and destroy infected cells.

HIPRA's vaccine can be kept at refrigerated temperatures between 2 and 8° C, facilitating storage and distribution. The technology used to produce the vaccine allows great versatility to adapt it to new potential future variants of the SARS-CoV-2 virus.

More about the RBDCOV project

RBDCOV is one of 11 selected projects supporting clinical trials for a new vaccine that can go beyond Europe's borders and create links with other European initiatives to effectively respond to the coronavirus crisis and strengthen existing research infrastructures. The European Commission has selected 11 projects in total involving 312 research teams from 40 countries. These projects fall under the Horizon Europe Framework Programme (2021-2027), Europe's largest research and innovation programme, and one of its priorities is to support urgent research on coronavirus and its variants.

More information:

Press Officer:
Susana Garayoa sgarayoa@zabala.eu
Phone number: M (+32) 484 61 91 64
(Brussels)

Amaia Cabezón acabezon@zabala.es
Phone number: M (+34) 673 744 542
(Pamplona)

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