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HIPRA starts a clinical trial to study its vaccine against COVID-19 as a 4th dose

200 volunteers will participate in the study and it will be carried out in 10 Spanish hospitals

With the aim of expanding the studies on the vaccine against Covid-19 developed by the biotechnology company HIPRA, a clinical trial will be carried out to assess the immunogenicity and safety of a 4th dose vaccination with the HIPRA vaccine in previously vaccinated people with three doses of the Comirnaty vaccine (Pfizer) or with two doses of the Comirnaty vaccine plus the HIPRA vaccine booster, which was administered in the framework of the previous Phase IIb clinical trial. This trial will serve to complete the results that the HIPRA vaccine has obtained to date.

10 Spanish hospitals will participate in this part of the study: Hospital Clínic de Barcelona (Barcelona, Catalonia), Hospital Universitari Dr. Josep Trueta (Girona, Catalonia), Hospital Universitari Vall d'Hebron (Barcelona, Catalonia), Hospital Germans Trias i Pujol – Can Ruti (Badalona, Catalonia), Hospital General Universitario Gregorio Marañón (Madrid, Community of Madrid), Hospital Universitario La Paz (Madrid, Community of Madrid), Hospital Universitario Príncipe de Asturias (Alcalá de Henares, Community of Madrid), Hospital Universitario de Cruces (Barakaldo, Basque Country), Carlos Haya Regional University Hospital in Malaga (Málaga, Andalusia) and Valencia University Clinical Hospital (Valencia, Valencian Community). The 10 centers will start the trial once approval is received from the Spanish Agency for Medicines and Health Products (AEMPS) and the Ethics Committee for Research with Medicines of the Hospital Clínic de Barcelona. The study is expected to begin in late summer.

In this study, in which 200 adults will participate, the safety, tolerability and efficacy of the booster dose of the HIPRA vaccine against Covid-19 will continue to be evaluated in a group of people vaccinated with three doses of Comirnaty (Pfizer) or with two doses of the Comirnaty vaccine plus the HIPRA vaccine booster. These two groups will be given the fourth dose of the HIPRA vaccine and the results will be compared with those obtained in a group of people vaccinated with three doses of Comirnaty (Pfizer). The volunteers will be followed for 30 weeks to assess long-term safety and immune response.

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People who want to participate in the trial must have received 3 doses of Comirnaty (Pfizer) (the last dose administered between the last 6 and 12 months) and must not have passed the Covid-19. Each hospital has enabled a space on its website so that interested people can register. Once the study is approved, they will be contacted to proceed.

HIPRA's Covid-19 vaccine is in the process of continuous review (or rolling review) by the European Medicines Agency (EMA). This is the step prior to marketing authorization.

The HIPRA vaccine

The Covid-19 vaccine being developed by HIPRA is an adjuvanted recombinant protein vaccine, based on a receptor binding domain (RBD) fusion heterodimer containing variants B.1.1.7 (alpha) and B.1.351 (beta) of SARS-CoV-2.

The HIPRA vaccine is stored at refrigerator temperature (between 2 and 8ºC), facilitating storage and distribution. The technology used allows great versatility to adapt it to new variants of the virus, if necessary in the future. The results obtained to date show that the vaccine produces neutralizing antibodies against the current VOCs (variants of "concern") and is also effective in preventing the disease.

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