Immunoglobulin clinical trial launched to prevent COVID-19 side effects

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Fom left to right: Silvia Castañeda, Inmaculada López-Montesinos, Elena Sendra, Juan Pablo Horcajada and Robert Güerri. Source: Hospital del Mar.

The Hospital del Mar Medical Research Institute (IMIM), Hospital del Mar, the University of California-Davis and the University of Texas have launched a clinical trial to analyze how useful a food supplement can be for preventing the worst side effects of COVID-19. The study is looking at bovine-derived immunoglobulins, which have been shown in animal models to reduce the inflammation caused by infection, progression to more severe forms of the disease, and post-COVID syndrome. The first patients participating in the Randomized Open-Label Clinical Study Evaluating the Impact of EnteraGam, a Nutritional Intervention containing Bovine Plasma-Derived Immunoglobulin CoNcentrate, on Clinical Outcomes In People with COVID19 (PICNIC Study) are already taking two daily doses of this supplement.

Dr. Robert Güerri, principal investigator in the trial, member of the Infectious Pathology and Antimicrobial Research Group at the IMIM-Hospital del Mar, and section head of the Infectious Diseases Service at Hospital del Mar, explains that "The aim of the treatment is to sequester and help eliminate the virus from one of its main reservoirs in the body, the gut." The presence of SARS-CoV-2 in this part of the body is due to the fact that the tissue here expresses a large quantity of one of its receptors, the ACE2 enzyme, which the virus uses to enter human cells and reproduce.

The food supplement (EnteraGam, manufactured by the US company EnteraHealth) is based on bovine serum (milk or colostrum from cows), which is very rich in immunoglobulins, also known as antibodies, one of the elements used by the immune system to detect and identify harmful viruses and bacteria. The product is freeze-dried, allowing the immunoglobulins to regain their original form when they reach the stomach, so that they can carry out their task of identifying the viral proteins and alerting the immune system to their presence.

Complement to standard treatments

This approach does not replace the treatments already being given to COVID-19 sufferers, but does complement and reinforce them. The patients take the supplement orally, twice a day for two weeks, and have a further two-week follow-up period. In total, the study will analyze 420 patients, of which 280 will take EnteraGam. The researchers' hypothesis, already demonstrated in animal models, is that taking EnteraGam "May reduce the risk of progressing from mild forms of the disease, which currently receive no specific treatment, to more severe forms, as well as inflammation, which causes the so-called cytokine storm, and the side effects of COVID-19, referred to as post-COVID-19 syndrome," explains Dr. Güerri.

The benefits of this option stem from three different mechanisms, as Dr. David Asmuth, Professor of

Medicine in the Department of Internal Medicine at the University of California-Davis and one of the driving forces behind the trial, explains. "An experiment using bovine coronavirus in calves showed a significant protective effect in cases that received immunoglobulins via bovine serum, probably due to the binding of antiviral antibodies. Secondly, bovine serum containing immunoglobulins reduces systemic inflammation in cases of intestinal viral infections. Finally, many COVID-19 patients have digestive system-related symptoms and this dietary supplement could address these symptoms directly, thereby reducing the systemic spread of SARS-CoV-2 from this point in the body." As Dr. Asmuth points out, "The gut-lung immune axis is well described and in vivo data has already demonstrated that immunoglobulin-rich bovine serum has a beneficial impact on lung disease in models similar to those seen with COVID-19."

Provided by IMIM (Hospital del Mar Medical Research Institute)

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