

Soberana-Pediatrics clinical trial begins in Cuban children between three and 11 years of age.

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Havana, June 28 (RHC)-- The first clinical trial undertaken in Cuba in children and adolescents, named Soberana-Pediatrics, continues this week with the inclusion of the second group of volunteers between the ages of three and 11.

This step takes place after the first 25 adolescents between 12 and 18 received the first dose without complications.

Yury Valdés Balbín, deputy director of the Finlay Vaccine Institute (IFV), told the press that 24, 48, and 72 hours and one week after immunization, the safety of the volunteers was evaluated and no serious adverse events were reported.

Based on these results, trial executives sent a report to the Center for the State Control of Medicines, Equipment, and Medical Devices (CECMED) requesting approval for the inclusion of the younger volunteers.

This Monday, Soberana 02 will be administered to the 25 selected subjects.

Valdes added that the safety result of the adolescents not only allows to start with the younger ages but also to extend the sample to another 150 children between 12 and 18 years of age, a process that will also begin this week.

Finlay Institute specialists explained that this is an open study because it will not use a placebo. All those involved will receive the vaccine candidates.

Soberana-Pediatrics Trial involves 350 children and adolescents, 50 in Phase I and 300 in Phase II, stages that will be developed in a staggered and overlapping manner, complying with the strict ethical protocol, good clinical practices and with the informed consent of parents or legal guardians; and in the case of adolescents and young people, also with their consent.

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