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CLINICAL TRIAL: "**Post-vaccination seroconversion study for SARS-CoV-2 using the RBD-Tuc immunotest**"

This presentation proposes a clnical study to evaluate seroconversion of subjects receiving the CoV-2 SARS vaccine platforms administered in the province of Tucumán, to study the behavior of different population groups against different intrinsic and extrinsic factors.

To meet this objective, you are invited to participate in this study where you will evaluate the level of antibodies you will develop after the immunization process.

Objetives:

-To evaluate the humoral immune response mediated by antibodies in different population groups and to estimate the average persistence time of the immunoglobulin G anti-RBD generated in the different types of vaccines administered in our province, during December 2020 and 2021.

- Correlate humoral immune response to extrinsic factors (type of vaccine platform)and intrinsic factors (nutritional status, age, sex, occupation, etc.)

Total Duration of the Study: Subject to the negativization of the antibodies that will be tested for a period of at least six months.

Blood samples: Blood samples (5 ml) obtained from either arm should be taken to measure the levels of antibodies against coronavirus. The sample will be taken in the hospitals that the health system enables for this project. The first sample has to be prior to vaccine placement to know baseline antibody levels. Blood samples will then be taken on days 14, 28, 60, 90, 180. The continuity of sampling will depend on the negativization of the antibody titre. The samples will be sent to the Public Health Laboratory under appropriate conditions where the RBD-Tuc test will be carried out. The results of the full study will be known after the completion of the study. Each participant will be able to know its results confidentially through a request to the responsible investigators.

Risks: There are no major risks of participating in this study. They are related to the removal of blood samples, pricking and less than 1% chance of hematoma or infection at the puncture site.

Benefits: There are no direct benefits for you, beyond contributing to the knowledge of how is the antibody response of people vaccinated against coronavirus in Tucumán.. Your participation in the study is voluntary, and if you agree to participate, you may opt out at any time during the study, or if you wish to opt out, this will not affect your attention or working conditions.. All your data will be confidential and only researchers will know your identity.. Your participation will have no cost to you and you will not be paid to participate.

The researchers responsible for the study who may be contacted at any time are:

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The researcher assures that his data will be confidential by assigning an identification code.

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I have been informed that I can participate in this research study to evaluate antibody levels in people receiving coronavirus vaccine.. The Ministry of Public Health of Tucumán and the researchers responsible for this study can suspend for different reasons the realization of this study at any stage of its development.. I consent to participate in this research study to evaluate antibody levels in people receiving coronavirus vaccines.

Patient name_____

DNI_____

Date_____

Name of hospital authority

_____

DNI_____

Date_____