

TecSalud begins Phase 3 trials of German CureVac vaccine in Mexico



The Clinical Research Area for Vaccines at TecSalud's Zambrano Hellion Hospital has begun clinical trials of the CureVac messenger RNA COVID vaccine.

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TecSalud

TecSalud, the health system of **Tecnológico de Monterrey**, has begun **administering the vaccine candidate to volunteers** participating in **Phase 3** clinical trials of the **mRNA COVID-19 vaccine** manufactured by the **CureVac laboratory**.

At 7.00 a.m. on February 15, the first volunteers arrived at the **Clinical Research Area for Vaccines at TecSalud's Zambrano Hellion Hospital**, which will be the center for administering vaccines and placebos to **3,000 volunteers**.

*"By participating in the testing of the German **mRNA** COVID-19 vaccine, a **protocol authorized by COFEPRIS**, Mexico is **leading Latin America**", explained **Dr. Guillermo Torre Amione, Rector of TecSalud and Vice President for***

Research at Tec de Monterrey.

*"**TecSalud** is proud to be actively participating in these kinds of research protocols for the diagnosis and treatment of COVID-19, with the **hope** of fighting the disease," he added.*

Similarly, **Dr. Torre** stressed that this initiative was the result of authorities, academics and civil society engaging in **public-private collaboration, synergy,** and **multidisciplinary efforts** to stop the advance of the pandemic.

*"**TecSalud** is proud to be actively participating in these kinds of research protocols for the diagnosis and treatment of COVID-19, with the hope of fighting the disease".*

Safety and efficacy of the German CureVac vaccine

Dr. **Servando Cardona**, **National Director of Clinical Research at TecSalud**, explained that this phase of clinical trials could be very promising.

*"**An efficacy rate of above 90%** has been confirmed in the trial results available at the moment, with a **higher range of safety** than that of other vaccines.*

*"This is thanks to **messenger RNA technology**, which allows us to imprint the **virus's RNA** in order to sequence its amino-acid chain and cause an immune response," he added.*

The expert said that this vaccine requires **deep-freezing** at **-80 degrees** but has been proven to be stable at higher temperatures, and can be **kept for up to three weeks**.

Dr. Cardona said that, without a doubt, this is going to be **a very important medical advance**: never before in the history of mankind have drugs been tested at such scale and in such a short time.

***“Recruiting 36,500 volunteers** in two months around the world is the result of extraordinary logistics. It means that the vaccine can get everywhere and be applied following the same processes and to the same standards,”* he said.



Dr. Servando Cardona, National Director for Clinical Research at TecSalud, and Dr. Michel Martínez, leader of the TecSalud COVID-19 Program and Lead Researcher for the Clinical Trial.

Dr. Michel Martínez, leader of **TecSalud’s COVID-19 Program** and lead researcher for the clinical trial, explained that **the vaccine is intended to be effective in preventing cases of COVID-19**, as well as measuring other parameters.

*“These are other so-called **secondary efficacy parameters**, which are: safety and, if the disease occurs, avoiding hospitalization or even death,”* he shared.

Messenger RNA vaccines, unlike traditional vaccines, do not require the injection of an attenuated or inactive virus, but rather convey information about proteins to teach our cells to produce the “spike protein” which lives on the surface of the virus.

“Since the body has already produced the protein, it has developed antibodies against it. When the virus arrives with this protein, it is rejected and cannot anchor itself,” said Dr. Martinez.

“An efficacy rate of above 90% has been confirmed in the trial results available at the moment, with a higher range of safety than that of other vaccines.”

An opportunity to change history

Ramiro Alejandro Aguirre García, 28, became the **first volunteer to receive the CVnCoV** Phase 3 test vaccine from the CureVac laboratory.

*“I was nervous but excited at the same time because it’s a **great opportunity to receive a COVID-19 vaccine** and to be able to help the entire population by participating in **finding a solution to the pandemic**,”* he said.

He reported having felt **no discomfort or side effect** during the 30-minute observation and recovery period.

Participating in the clinical trial meant Ramiro **had the possibility of getting the vaccine in advance**. Normally, due to his young age, he would have to follow the federal Ministry of Health’s [**vaccination plan**](#) and wait to be vaccinated in coming months.

He encouraged the general public to participate in clinical research studies.

“I think there has been a lot of misinformation among the public about the vaccines not being good, having been created too quickly, and that there are many people who don’t want to be vaccinated.”

*“It’s important to change people’s mentality, and to share the message **that vaccines help and provide hope for the entire population.***

“Vaccines help and provide hope for the entire population.”

Volunteer safety

Participants in the **CureVac** mRNA vaccine **Phase 3 clinical trial** followed a detailed step-by-step process to register in order to **ensure the safety** of all participants.

First, they sent their contact information through the [official TecSalud site](#); afterwards, they filled out a **registration form** which was evaluated. All volunteers were notified by email about whether they were eligible to participate in the study and if they met the **criteria specified by CureVac**.

Volunteers confirmed as eligible **scheduled their first visit** to the Clinical Research Area for Vaccines at **TecSalud’s Zambrano Hellion Hospital** online, to undergo a medical evaluation and **sign consent forms**.

If the evaluation did not yield any additional data excluding them, participants could be given the **first dose** of the research product, which could be a **vaccine or a placebo**.

Two doses will be given, the second approximately one month after the first. The **volunteers** will make a total of **5 visits** during a period of **393 days**, as well as keeping an electronic diary and receiving **advice** and **follow-up** via **phone calls**.



Ramiro Aguirre during the medical consultation validating whether he meets the eligibility criteria specified by the CureVac laboratory.

The scope of the Phase 3 CureVac Vaccine Clinical Trial

Of the **8,000 doses** that will be given in Mexico, **3,000 will be administered in Monterrey** by TecSalud, which will lead the study in the city.

The rest will be given by other **research centers** throughout Mexico. This will meet the requirements for the number of volunteers in Mexico which form part of the **36,500 volunteers around the world**.

It is a **randomized double-blind** clinical trial, which means that an assigned **experimental group** of participants receive the vaccine and a **control group** receive a placebo.

The **double-blind method** is used as part of the scientific process so that neither the participants nor the researchers know who belongs to the control group and who

belongs to the experimental group. This **eliminates bias on both the part of the participants and the researchers.**



Participating volunteers go through an evaluation process in order to be given the research product.

To determine efficacy, the number of **SARS-CoV-2** infections in the group that received the vaccine **will be compared** with **the group that received the placebo.**

*"If we demonstrate efficacy, the clinical trial could **be ended early**, between **the eighth and ninth months. We would then give the placebo patients the vaccine**, so they could possibly receive it before the end of the 13 months,"* explained the study's lead researcher, Michel Martínez.

Dr. Torre said that understanding whether the Mexican public will respond without major complications, without major side effects, and with the same effectiveness as

other populations, is very important to the Mexican community.

*“We have studied few Phase 3 vaccines in Mexico. CureVac is one of them, and it is the **only one that uses RNA technology** tested through clinical studies undertaken in Mexico.*

*Having a **vaccine in an experimental phase in Mexico** will provide **additional data** to the results of international studies. It will give us **clear information about how it will benefit the Mexican public,**”* concluded Dr. Torre.



The group of doctors participating in the German CureVac vaccine Phase 3 clinical trial.

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