

(Excerpts below are from <https://www.niaid.nih.gov/news-events/phase-3-clinical-trial-investigational-vaccine-covid-19-begins>)

## **Clinical Trial of Investigational Vaccine for COVID-19 Begins Multi-Site Trial to Test Candidate Developed by Moderna and NIH**

July 27, 2020

“A Phase 3 clinical trial designed to evaluate if an investigational vaccine can prevent symptomatic coronavirus disease 2019 (COVID-19) in adults has begun. The vaccine, known as mRNA-1273, was co-developed by the Cambridge, Massachusetts-based biotechnology company Moderna, Inc., and the National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health. The trial, which will be conducted at U.S. clinical research sites, is expected to enroll approximately 30,000 adult volunteers who do not have COVID-19.”

“NIAID scientists developed the stabilized SARS-CoV-2 spike immunogen (S-2P). SARS-CoV-2 is the virus that causes COVID-19; the spike protein on its surface facilitates entry into a cell. Moderna’s mRNA-1273 uses the mRNA (messenger RNA) delivery platform to encode for an S-2P immunogen. The investigational vaccine directs the body’s cells to express the spike protein to elicit a broad immune response. A Phase 1 clinical trial found the candidate vaccine to be safe, generally well-tolerated and able to induce antibodies with high levels of virus-neutralizing activity. Moderna initiated Phase 2 testing of the vaccine in May 2020.”

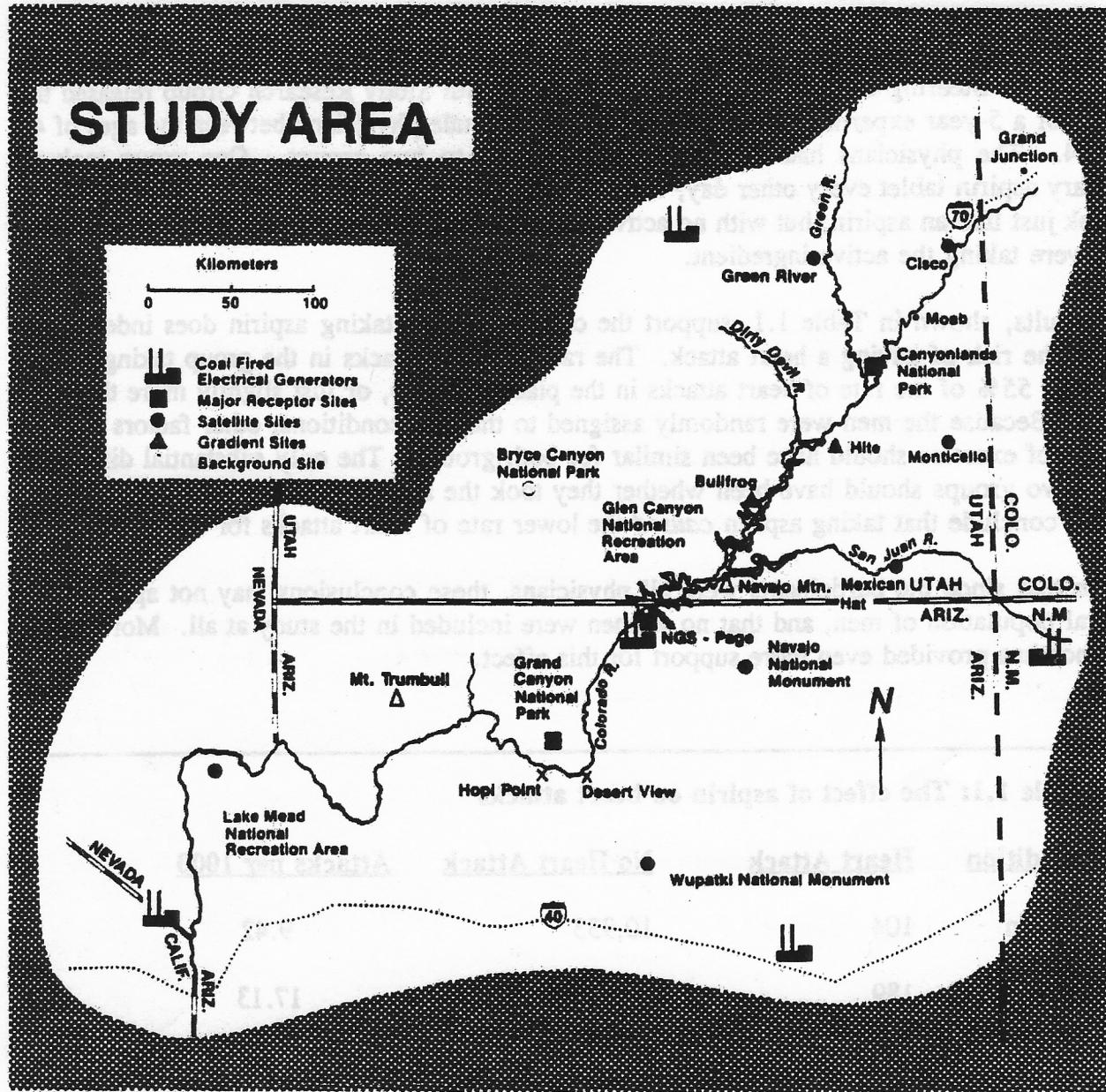
“The trial is designed to evaluate the safety of mRNA-1273 and to determine if the vaccine can prevent symptomatic COVID-19 after two doses. As secondary goals, the trial also aims to study whether the vaccine can prevent severe COVID-19 or laboratory-confirmed SARS-CoV-2 infection with or without disease symptoms. The trial also seeks to answer if the vaccine can prevent death caused by COVID-19 and whether just one dose can prevent symptomatic COVID-19, among other objectives.”

“Trial volunteers will receive two intramuscular injections approximately 28 days apart. Participants will be randomly assigned 1:1 to receive either two 100 microgram (mcg) injections of mRNA-1273 or two shots of a saline placebo. The trial is blinded, so the investigators and the participants will not know who is assigned to which group.”

Here’s one possible way to summarize the data:

<b>Group</b>	<b>Yes</b>	<b>No</b>	<b>Total</b>
Vaccine	?	?	15,000
Placebo	?	?	15,000

# STUDY AREA



**RELIABILITY ACURA - CHEVROLET**