**Analysis of “Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine”**

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In February 2021, the COVE Study Group published “Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine” to determine the effectiveness of the Moderna vaccine at preventing mild to severe Covid-19 illness, and to describe safety concerns associated with vaccination.

The COVE Study Group conducted a “randomized, stratified, observer-blinded, placebo-controlled” experiment involving a sample of 30,420 medically stable adults at an appreciable risk for SARS-CoV-2 infection or its complications. The sample was demographically representative of the United-States population. Participants were assigned in a 1:1 ratio to a treatment group and a baseline control group; because groups were equalized with respect to confounding variables, the treatment group and the control group were very similar at first. Participants in the treatment group received two intramuscular injections of the Moderna vaccine approximately 28 days apart; participants in the control group received two injections of inactive placebo. Participants received injections at 99 centers across the United States.

The independent / explanatory variable was whether or not a study participant received the Moderna vaccine, and for each participant took on one of the nominal, categorical, qualitative values “Yes” or “No”. The dependent / response variable was whether or not a study participant developed Covid-19 illness by 14 days after their section injection, and took on one of the nominal values “Yes” or “No”.

The Center for Disease Control (CDC) defines the risk of a disease as the ratio of the number of cases of the disease in a group to the number of people in the group [1]. The CDC defines the effectiveness (as opposed to the efficacy, because the study was carried out under less than perfectly controlled conditions) as

where is the risk of disease among unvaccinated persons in a control group and is the risk of disease among vaccinated persons in a treatment group. Without change to the effectiveness, each of these risks can be converted to cases per person-year by dividing that risk by the average number of years that each study participant participated (about , or ). According to the study, the number of participants in the control group who were included in a per-protocol analysis and developed symptomatic Covid-19 illness by 14 days after their second injection was . The number of participants in the control group who were included in the per-protocol analysis was . The number of participants in the treatment group who were included in the per-protocol analysis and developed symptomatic Covid-19 illness by 14 days after their second injection was 11. The number of participants in the treatment group was 14,134. Observer blinding was practiced to prevent influence on these numbers by symptom observers knowing whether participants had received vaccine or placebo. The risk for the control group . The risk for the treatment group . Then

Aside from moderate, transient reactogenicity after vaccination, no safety concerns were identified.

A hypothesis test involving the 14,073 participants in the control group who were involved in the per-protocol analysis and the 14,134 participants in the treatment group who were involved in the per-protocol analysis, the null hypothesis that “the effectiveness of the Moderna vaccine is 30 percent or less”, and the alternative hypothesis that “the effectiveness of the Moderna vaccine is greater than 30 percent” was conducted. An effectiveness of 94.1 percent and a one-sided *P* value of less than 0.001 was determined for the sample of 28,207 participants involved in the per-protocol analysis; the null hypothesis was rejected. The results of the hypothesis test were statistically significant; there was sufficient evidence to conclude that the effectiveness of the Moderna vaccine was greater than 30 percent.

An effectiveness indicates the reduction of the likelihood of exhibiting Covid-19 illness, across a large group, from receiving the Moderna vaccination. Per the CDC, “Vaccine efficacy and vaccine effectiveness measure the proportionate reduction in cases among vaccinated persons”. On this basis of a -percent reduction in in cases among vaccinated persons, and on the basis that, per the COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University (JHU), the ratio of the number of global deaths due to COVID-19 and the number of global recoveries is 0.037, the Moderna vaccine is highly recommended.

**References**

1. Center for Disease Control; May 18, 2012. “Vaccine efficacy or vaccine effectiveness”. *Principles of Epidemiology in Public Health Practice, Third Edition: An Introduction to Applied Epidemiology and Biostatistics*. Access 04/23/21 via <https://www.cdc.gov/csels/dsepd/ss1978/lesson3/section6.html>.