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Clinical trial during pandamic will give descriptions of Abudhabi government effort during pandemic including the clinical trial for humanity project

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Objective: To evaluate the efficacy and adverse events of 2 inactivated COVID-19 vaccines. DESIGN, SETTING, AND PARTICIPANTS Prespecified interim analysis of an ongoing randomized, double-blind, phase 3 trial in the United Arab Emirates and Bahrain among adults 18 years and older without known history of COVID-19. Study enrollment began on July 16, 2020. Data sets used for the interim analysis of efficacy and adverse events were locked on December 20, 2020, and December 31, 2020, respectively.

Interventions: Participants were randomized to receive 1 of 2 inactivated vaccines developed from SARS-CoV-2 WIV04 (5 μg/dose; n = 13 459) and HB02 (4 μg/dose; n = 13 465) strains or an aluminum hydroxide (alum)–only control (n = 13 458); they received 2 intramuscular injections 21 days apart.

Main outcomes and measures: The primary outcomewas efficacy against laboratory-confirmed symptomatic COVID-19 14 days following a second vaccine dose among participants who had no virologic evidence of SARS-CoV-2 infection at randomization. The secondary outcome was efficacy against severe COVID-19. Incidence of adverse events and reactions was collected among participants who received at least 1 dose.

Results: Among 40 382 participants randomized to receive at least 1 dose of the 2 vaccines or alum-only control (mean age, 36.1 years; 32 261 [84.4%] men), 38 206 (94.6%) who received 2 doses, contributed at least 1 follow-up measure after day 14 following the second dose, and had negative reverse transcriptase–polymerase chain reaction test results at enrollment were included in the primary efficacy analysis. During a median (range) follow-up duration of 77 (1-121) days, symptomatic COVID-19 was identified in 26 participants in the WIV04 group (12.1 [95%CI, 8.3-17.8] per 1000 person-years), 21 in the HB02 group (9.8 [95%CI, 6.4-15.0] per 1000 person-years), and 95 in the alum-only group (44.7 [95%CI, 36.6-54.6] per 1000 person-years), resulting in a vaccine efficacy, compared with alum-only,of 72.8%(95%CI, 58.1%-82.4%) for WIV04 and 78.1%(95%CI, 64.8%-86.3%) for HB02 (P < .001 for both). Two severe cases of COVID-19 occurred in the alum-only group and none occurred in the vaccine groups. Adverse reactions 7 days after each injection occurred in 41.7%to 46.5%of participants in the 3 groups; serious adverse events were rare and similar in the 3 groups (WIV04: 64 [0.5%]; HB02: 59 [0.4%]; alum-only: 78 [0.6%]).

Conclusion: In this prespecified interim analysis of a randomized clinical trial, treatment of adults with either of 2 inactivated SARS-CoV-2 vaccines significantly reduced the risk of symptomatic COVID-19, and serious adverse events were rare

Biography

Dr. Salah Eldin Omar Hussein joined as Assistant Professor, Department of Medical Laboratory Sciences, College of Health Sciences, and Gulf Medical University in January 2022 with more than 20 years of teaching and research experience in area of Medical laboratory Science with different academic positions in Sudan and Saudi Arabia. He has more than 20 publications (articles, chapters and books) in internationally recognized journals and publishers.