COVID-19 Evidence Digest 05/14/21

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Efficacy of NVX-CoV2373 COVID-19 Vaccine against the B.1.351 Variant (NEJM)

Bottom Line: The NVX-CoV2373 (Novavax) vaccine was overall found to be effective against COVID-19 after the first dose, with the vaccine being more effective among those who are HIV-negative.

Details: This study was a phase 2a–b clinical trial of the Novavax (NVX-CoV2373) vaccine in South Africa. Adults older than 18 years old were randomly assigned to receive either two doses of the vaccine or a placebo; 4,387 participants received at least one dose of either the vaccine or placebo. At baseline, 2,684 participants had a negative SARS-CoV-2 antibody test. Among these 2,684 patients, 94% were HIV-negative and 6% were HIV-positive. The vaccine was found to be 49.4% effective (95% CI, 6.1-72.8) against COVID-19 with 15 participants who received the vaccine and 29 participants who received the placebo developing mild or moderate COVID-19. Of those who were HIV-negative, the vaccine was 60.1% effective (95% CI, 19.9-80.1). The vaccine was also found to be 51.0% (95% CI, -0.6-17.2) effective against the B.1.351 (South African) variant, which made up most of the COVID-19 cases. The most commonly reported adverse event was injection site pain with serious adverse events being rare and not reportedly related to the vaccine.

Key Takeaways:

- The NVX-CoV2373 vaccine was found to be about 60% effective against COVID-19 among those who were HIV-negative.
- The vaccine was also found to be about 51% effective against the B.1.351 (South African) COVID-19 variant.
- Additional and follow-up studies are needed to further understand the effectiveness of the NVX-CoV2373 vaccine, particularly against severe COVID-19.

Updated Recommendations from the Advisory Committee on Immunization Practices for Use of the Janssen (Johnson & Johnson) COVID-19 Vaccine After Reports of Thrombosis with Thrombocytopenia Syndrome Among Vaccine Recipients — United States, April 2021 (MMWR)

Details: On April 13, CDC and FDA recommended a pause on the use of Janssen COVID-19 vaccine given cases of cerebral venous sinus thrombosis (CVST) with thrombocytopenia in 6 vaccine recipients. There are 15 reports of thrombosis with thrombocytopenia syndrome (TTS) after Janssen COVID-19 vaccination, 13 of which occurred in women younger than 50 years old. Limiting vaccine use to specific populations based on age and sex could reduce cases of TTS, but would also create additional barriers for public health implementation, limit personal choice, and disproportionately affect populations that may have increased barriers to vaccination and returning for a second dose. On April 23, ACIP concluded that benefits of using the Janssen COVID-19 vaccine in all persons aged 18 and older outweighed the risks. ACIP recommends provider-patient education regarding risk of TTS after vaccination among women aged 18-49 as well as discussion about other available COVID19 vaccines. The FDA Emergency Use Authorization now includes a warning for rare clotting events among women aged 18-49 years receiving the Janssen COVID-19 vaccine.

Optimal dose and safety of molnupiravir in patients with early SARS-CoV-2: a phase 1, dose-escalating, randomised controlled study (MedRxIV)

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Bottom Line: Adult with confirmed COVID-19 in the outpatient setting treated with the oral antiviral molnupiravir tolerated it well without serious adverse events.

Details: In this phase Ib/IIa, dose-escalating, open-label, randomized-controlled study, 18 adult participants with lab confirmed SARS-CoV-2 infection within 5 days of symptom onset were randomized 2:1 to 400, 600, 800mg doses of molnupiravir (orally, twice daily for 5 days) versus placebo during July 17-October 30, 2020. Molnupiravir was well tolerated at all doses with no serious or severe adverse events; 4 of 4 (100%), 4 of 4 (100%) and 1 of 4 (25%) of the participants receiving 300, 600 and 800mg molnupiravir respectively, and 5 of 6 (83%) controls, had at least one adverse event but they were all mild. The dose of 800mg was selected to move forward with subsequent clinical trials.

Key Takeaways: Oral molnupiravir is an exciting prospect as an oral antiviral treatment targeting SARS-CoV-2 and was well tolerated without any serious adverse events among adult outpatients with mild-moderate COVID-19 infection.

Non-steroidal anti-inflammatory drug use and outcomes of COVID-19 in the ISARIC Clinical Characterisation Protocol UK cohort: a matched, prospective cohort study (Lancet)

Bottom Line: In a large, prospective, multicenter cohort study, the pre-existing (within 2 weeks before hospitalization) use of non-steroidal anti-inflammatory drugs (NSAIDs) was not associated with higher mortality or increased severity of COVID-19 disease among hospitalized patients with confirmed or highly suspected COVID-19.

Details: In this prospective, multicenter cohort study of the UK, 78,674 patients (any ages) were hospitalized with confirmed or highly suspected SARS-CoV-2 infection during January 17–August 10, 2020. Among these patients, 72,179 of them had death outcomes available and were included for this study. The primary study interest was to evaluate whether NSAIDs was associated with in-hospital mortality. Pre-existing use was defined as the use of NSAIDs within the 2 weeks before hospitalization. Of the 71,915 patients included, 5.8% (n=4,211) had pre-existing use of NSAIDs. In the NSAID group, 30.4% (n=1,279) of patients died whereas 31.3% (n=21,256) of patients in the no NSAIDs group died. A 1:1 propensity score matching was used to select a cohort of comparable NSAIDs non-users (n = 4,205) and compare it with 4,205 NSAIDs users (6 patients out of 4,211 were excluded due to missing variables required for matching). No significant differences were found between the two matched groups at admission. Controlling for age, sex, ethnicity/race, and selected comorbidities, NSAID use was not associated with worse in-hospital mortality (matched Odds Ratio [OR]: 0.95; 95% CI: 0.84-1.07). For secondary outcome analyses, NSAID use was not associated with critical care admission (OR: 1.01; 95% CI: 0.87-1.17), invasive ventilation use (OR: 0.96; 95% CI: 0.80-1.17), non-invasive ventilation use (OR: 1.12; 95% CI: 0.96-1.32), oxygen requirement (OR: 1.00; 95% CI: 0.89-1.12), or onset of acute kidney injury (1.08; 95% CI: 0.92-1.26).

Key Takeaways:

- Pre-existing use of NSAID use is not associated with higher mortality or increased critical care admission, requirement for invasive ventilation, requirement for non-invasive ventilation use, or occurrence of acute kidney injury.