CHIPS REGIMEN

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BRIDGING THE GAP NOVAVAX COVID-19 VACCINE DEMONSTRATES 90% OVERALL EFFICACY

Novavax's recombinant nanoparticle protein-based COVID-19 vaccine showed an overall efficacy of 90.4% and 100% efficacy against moderate and severe disease.

Novavax's recombinant nanoparticle protein-based COVID-19 vaccine showed an overall efficacy of 90.4%, according to the results of a phase 3 study.

The investigational NVX-CoV2373 met the primary end point in its PREVENT-19 phase 3 trial, which enrolled 29,960 participants across the United States and Mexico. Additional key findings showed 100% protection against moderate and severe COVID-19. Novavax plans to file for regulatory authorizations in the third quarter of 2021.

In the PREVENT-19 trial, a total of 77 COVID-19 cases were observed: 63 in the placebo group and 14 in the vaccine group. All cases observed in the vaccine group were mild, and 10 moderate cases and 4 severe cases occurred in the placebo group. The primary end point for PREVENT-19 was the first occurrence of polymerase chain reaction (PCR) confirmed symptomatic COVID-19 with onset at least 7 days after the second dose in serologically negative adult participants at baseline.

According to Novavax, the efficacy end points were accrued from January 25 through April 30, 2021, when the Alpha (B.1.1.7) variant became the predominant strain in the United States, and other strains such as variants of interest (VoI) and variants of concern (VoC) were on the rise. Against VoC/VoI, which represented 82% of the cases, vaccine efficacy was 93.2% (95% CI: 83.9, 97.1), according to the results. NVX-CoV2373 also demonstrated efficacy among high-risk populations, defined as those over age 65, under age 65 with certain comorbidities, or having life circumstances with frequent COVID-19 exposure. Vaccine efficacy among

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this group was 91.0% (95% CI: 83.6, 95.0), with 62 COVID-19 cases in the placebo group and 13 COVID-19 cases in the vaccine group.

Regarding safety, preliminary data from the study showed the vaccine to be generally well tolerated. No single adverse effect (AE) was reported by more than 1% of participants. Injection site pain and tenderness, generally mild to moderate in severity, were the most common local reactions, lasting less than 3 days. Fatigue, headache, and muscle pain were the most common systemic symptoms, which generally lasted less than 2 days.

PREVENT-19 confirms that NVX-CoV2373 offers a reassuring tolerability and safety profile," said Gregory M. Glenn, MD, president of research and development, Novavax. "These data show consistent, high levels of efficacy and reaffirm the ability of the vaccine to prevent COVID-19 amid ongoing genetic evolution of the virus. Our vaccine will be a critical part of the solution to COVID-19 and we are grateful to the study participants and trial staff who made this study possible, as well as our supporters, including the US government."

A placebo-controlled portion of PREVENT-19 is ongoing in adolescents 12 to less than 18 years of age.

Reference:

1. Novavax COVID-19 Vaccine Demonstrates 90% Overall Efficacy and 100% Protection Against Moderate and Severe Disease in PREVENT-19 Phase 3 Trial. News Release. Novavax; June 14, 2021. Accessed

STUDENTS CORNER

New Drug Approval Update: Bempedoic Acid for Hypercholesterolemia.

Bempedoic acid is an adenosine triphosphate-citrate lyase inhibitor that is administered orally as an adjunct to diet and maximally tolerated statin therapy for the treatment of heterozygous familial hypercholesterolemia or established cardiovascular disease in patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C). The first step in treating hypercholesterolemia is dietary modification. If this strategy fails, the most preferred treatment is a statin, bempedoic acid is indicated as an adjunct, to diet and maximally tolerated statin therapy".

Lemborexant for Insomnia.

Lemborexant is an orexin receptor antagonist indicated to be administered orally for the treatment of insomnia in adults. "Lemborexant is the second drug that is classified as an orexin receptor antagonist, joining suvorexant, which was initially approved and marketed about 7 years ago. There are various patterns of insomnia. Patterns associated with sleep onset describe patients who have difficulty falling asleep, whereas sleep maintenance issues occur when patients have a hard time staying asleep. In the case of lemborexant, data showed that the new agent has both fast onset and long duration of action. In a clinical trial, lemborexant was more effective than zolpidem extended release 6.25 mg.

Lumateperone for Schizophrenia.

Lumateperone tosylate is indicated to be administered orally for the treatment of schizophrenia in adults. The drug is similar to other orally administered atypical antipsychotic agents, including risperidone. "Most of the antipsychotic drugs have actions; typically, it's a combined effect on certain serotonin receptor subtypes and certain dopamine receptors. Compared with risperidone, lumateperone may be less likely to cause extrapyramidal symptoms, weight gain, and hyperprolactinemia. As for its downsides, lumateperone may be less effective.

Ozanimod for Multiple Sclerosis.

Ozanimod is a sphingosine 1-phosphate (S1P) receptor modulator administered orally. There are a few different subtypes of S1P receptors. "Whereas the first of these agents, fingolimod, exhibits activity at 4 of the 5 known receptor subtypes of S1P, the newest agent has a more

selective action in acting at S1P receptor subtypes 1 and 5. Ozanimod is less likely to cause cardiovascular AEs than other MS treatments. Not only that, but treatment with ozanimod also doesn't require cytochrome P450 2C9 genotype testing, unlike some of the other drugs indicated for MS. Ozanimod is administered for relapsing forms of MS, which represents approximately 85% of patients. One disadvantage of ozanimod is its potential to interact with a wider range of other drugs. Additionally, as an immunomodulator drug, ozanimod must be monitored for the possible increased risk of infection.

CLINICAL CONNECTION

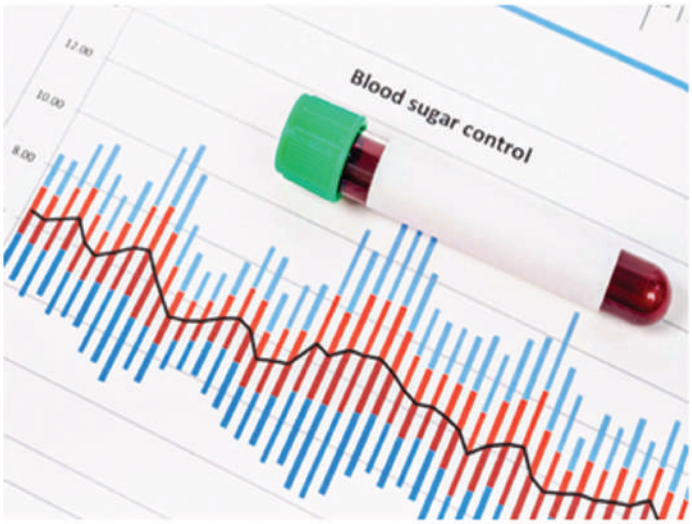
Lasmiditan Hemisuccinate for Migraine

Lasmiditan is a serotonin 1F receptor agonist approved for the treatment of adult patients with acute migraine with or without aura. Advantages of lasmiditan: • It has a more selective action and has not been associated with vasoconstrictive effects. • It is safer for use in a broader range of patients compared with similar drugs. • It is less likely to lead to chest, throat, neck, or jaw pain or pressure, or lower seizure threshold. However, lasmiditan has some drawbacks. It has not been directly compared with triptans in clinical studies. Other limitations are its higher likelihood to interact with heart rate– lowering drugs and to cause a central nervous system depressant action.

Hopkins Model for Glucose Management Reduces Complications, Improves Patient Outcomes

An observation that cardiac surgery patients at The Johns Hopkins Hospital who had diabetes appeared to have longer lengths of stay launched the Inpatient Diabetes Management Service. This multipronged, multidisciplinary approach to glucose management — which started as a pilot in 2003 — has grown into a national model for inpatient diabetes care.

For 15 years, the effort has championed safe glucose control for patients in the hospital, which has benefits such as decreased rates of dangerously low blood sugars, shorter hospitalizations and a reduced risk for external wound infections following surgery.



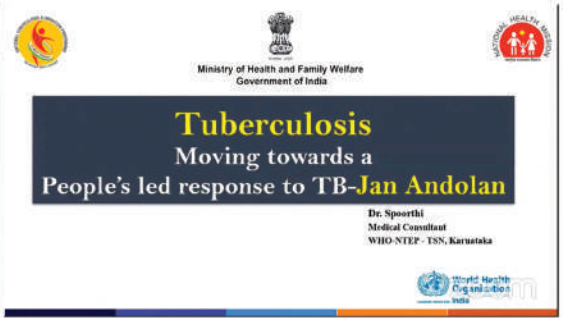
After noting a 58 percent reduction in lengths of stay in patients with diabetes during the first year of the program, a greater percentage of glucoses in the recommended target range and a lower rate of hypoglycemia, made a unified diabetes medication order set, and the creation of four policies to guide safe care of glucose management in hospitalized patients. They included: 1) guidance to allow nurses to begin quick treatment of hypoglycemia, 2) unified IV insulin infusion policies for the ICUs, 3) policies for management of hyperglycemia and 4) guidelines for allowing patients admitted with insulin pumps to continue self-management.

The work was unique because "at the time, there was not yet a set of inpatient glucose management guidelines". "The first set of guidelines from the American Diabetes Association was released in 2004, but because john Hopkins was on the forefront of using a multidisciplinary team approach to glucose management.

The Johns Hopkins model features a centralized glucose management program, coupled with targeted education and clinical decision support for staff, as well as process measures to evaluate interventions. It has resulted in average patient-day weighted mean blood glucose (PDWMBG) below the recommended maximum of 180 milligrams per deciliter in patients with diabetes and hyperglycemia; a significant 7.8 milligrams per deciliter decrease in PDWMBG in patients with hyperglycemia; and an 18.8 percent sustained reduction in hypoglycemia event rates, according to a 2012 study.

Reference:

https://www.hopkinsmedicine.org/endocrinology_diabetes_metabolism/patient_care/specialty_centers/inpatient_diabetes_management.html



Webinar on National Tuberculosis Eradication Programme

World Animal Day

Corona Awareness Talk by Dr Ramakrishna

Motivational Talk by Dr. Jagannath Rao

Webinar on Leveraging Students' Learning Experience Using Microlearning Strategies

Womens Day at CHIPS

Workshop by Pharma Training Institute

Waste Recycling

GPAT 2021 Rankers

Episource Placements

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