A Study Looking at the Efficacy, Immune Response, and Safety of a COVID-19 Vaccine in Adults at Risk for SARS-CoV-2

Status: Recruiting

Eligibility Criteria

Sex: All
Age: 18 Years and over

Healthy Volunteers: This study is also accepting healthy volunteers

Inclusion Criteria:

• Adults ≥ 18 years of age at screening who, by virtue of age, race, ethnicity or life circumstances, are considered at substantial risk of exposure to and infection with SARS-CoV-2.
• Willing and able to give informed consent prior to study enrollment and to comply with study procedures.
• Participants of childbearing potential (defined as any participant who has experienced menarche and who is NOT surgically sterile [ie, hysterectomy, bilateral tubal ligation, or bilateral oophorectomy] or postmenopausal [defined as amenorrhea at least 12 consecutive months]) must agree to be heterosexually inactive from at least 28 days prior to enrollment and through 3 months after the last vaccination OR agree to consistently use a medically acceptable method of contraception from at least 28 days prior to enrollment and through 3 months after the last vaccination.
• Is medically stable, as determined by the investigator (based on review of health status, vital signs [to include body temperature], medical history, and targeted physical examination [to include body weight]). Vital signs must be within medically acceptable ranges prior to the first vaccination.
• Agree to not participate in any other SARS-CoV-2 prevention trial during the study follow-up.

Exclusion Criteria:

• Unstable acute or chronic illness. Criteria for unstable medical conditions include: 1. Substantive changes in chronic prescribed medication (change in class or significant change in dose) in the past 2 months. 2. Currently undergoing workup of undiagnosed illness that could lead to diagnosis of a new condition.
• Participation in research involving an investigational product (drug/biologic/device) within 45 days prior to first study vaccination.
• History of a previous laboratory-confirmed diagnosis of SARS-CoV-2 infection or COVID-19.
• Received influenza vaccination or any other adult vaccine within 4 days prior to or within 7 days after either study vaccination.
• Autoimmune or immunodeficiency disease/condition (iatrogenic or congenital) requiring ongoing immunomodulatory therapy.
• Chronic administration (defined as > 14 continuous days) of immunosuppressant, systemic glucocorticoids, or other immune-modifying drugs within 90 days prior to first study vaccination.
• Received immunoglobulin, blood-derived products, or immunosuppressant drugs within 90 days prior to first study vaccination.
• Active cancer (malignancy) on therapy within 1 year prior to first study vaccination (with the exception of malignancy cured via excision, at the discretion of the investigator).
• Any known allergies to products contained in the investigational product.
• Participants who are breastfeeding, pregnant or who plan to become pregnant within 3 months following last study vaccination.
• Any other condition that, in the opinion of the investigator, would pose a health risk to the participant if enrolled or could interfere with evaluation of the trial vaccine or interpretation of study results.
• Study team member or first-degree relative of any study team member (inclusive of Sponsor, and study site personnel involved in the study).
• Current participation in any other COVID-19 prevention clinical trial.

Conditions & Interventions

Interventions:
• Biological: SARS-CoV-2 rS/Matrix-M1 Adjuvant, Other: Placebo

Conditions:
• SARS-CoV Infection, Covid19

Keywords:
• Coronavirus, Prevent-19

More Information

Contact(s): researchscreening@fairview.org

Phase: Phase 3
IRB Number:
System ID: NCT04611802

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