NOVAVAX
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COVID-NanoFlu™ Combination Vaccine
Clinical Trial Factsheet

About Novavax and this study

Novavax, a biotechnology company dedicated to developing and commercializing next-generation vaccines for serious infectious diseases, has launched a Phase 1/2 trial to evaluate the safety and immunogenicity of a COVID-NanoFlu Combination Vaccine with Matrix-M™ adjuvant. The trial will be conducted in healthy participants 50 through 70 years of age.

Study at a Glance

Trial Focus
Evaluating safety and immunogenicity of a combined vaccine targeting Influenza and SARS-CoV-2

Participants
640 older adults (age 50-70) in Australia

Approach
A range of doses to evaluate optimized formulation(s) for further study

Timing
Starting September 2021, 6-month duration

Background

Combination vaccines reduce the number of shots required to protect against multiple diseases. Simplifying immunizations into fewer shots may make it more likely that people get recommended vaccinations on time, reducing delays in protection[1,2].

Novavax is developing NanoFlu, a quadrivalent nanoparticle influenza vaccine (qNIV), and NVX-CoV2373, a nanoparticle COVID-19 vaccine. As both influenza and SARS-CoV-2 continue to circulate and evolve, combining these vaccines into a single shot could offer protection against both diseases.

This study follows Novavax' successful NanoFlu Phase 3 trial in the US[3], and successful Phase 3 trials of NVX-CoV2373 in the United Kingdom[4] and in the United States and Mexico[5]. A sub-study of the UK Phase 3 showed that co-administration of NVX-CoV2373 and a seasonal influenza vaccine was well-tolerated and preserved vaccine efficacy[6]. A pre-clinical study of the combination vaccine demonstrated robust responses to both influenza A and B and protected against the SARS-CoV-2 virus[7].

Clinical Trial Details

This study will enroll 640 healthy adults, 50-70 years of age, inclusive, at up to 12 sites in Australia. Participants will be baseline seropositive for, or fully immunized against, COVID-19.

The trial will randomize participants across 16 vaccine groups: 14 groups will evaluate different dose formulations of the combination vaccine; 2 groups will receive only the reference formulations of NVX-CoV2373 or NanoFlu, respectively, as a benchmark. This study will enable selection of one or more optimized combination vaccine dose formulation to advance info further clinical development.

COVID-NanoFlu Combination Vaccine Details

- The Novavax COVID-NanoFlu Combination Vaccine uses the full-length, stabilized recombinant Spike (rS) protein of the SARS-CoV-2 virus, and 4 wild-type recombinant Hemagglutinin (rHA) proteins from the influenza virus, as antigens. Antigens are organized into distinct nanoparticle complexes recognized by the immune system.
- Novavax' Matrix-M adjuvant increases and broadens the immune response and has been shown to stimulate high levels of neutralizing antibodies and T-cell responses[8].
- The combination vaccine will be administered with 2 injections, 56 days apart.
- Different amounts of both rS and rHA antigens are being evaluated to optimize vaccine dose. The amount of Matrix-M adjuvant remains constant.
- Vaccine proteins cannot replicate and cannot cause disease.
- The vaccine is maintained at standard refrigeration conditions (2-8°C).

Thank You

Novavax is grateful to the thousands of people around the world who are volunteering for our vaccine studies. We thank the U.S. Government and the Coalition for Epidemic Preparedness Innovations (CEPI) for their significant support of our work.

References

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