Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

Title of Trial: A Phase 1 Study to Evaluate the Immunogenicity and Safety of Monovalent A/Anhui/1/2013 (H7N9) Virus-Like Particle (VLP) Avian Influenza Antigen (Recombinant) in Healthy Adults With and Without Adjuvant 1

Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov): NCT01897701

Authors/sponsors:

Study Design: Randomized, Observer-Blinded, Dose-Ranging, Seven arms

Vaccine: H7N9
  Manufacturer: Novavax

  Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector): virus-like particle

  Adjuvant: to be used in some groups of vaccinees

Delivery system/site: IM

Doses (antigen and adjuvant): low, intermediate and high doses of antigen; two identical doses at day 0 and 21 day,

Study population: 280

  Age range: 18 Years and older  Health status: Health volunteers

Specific inclusion/exclusion criteria:

Inclusion Criteria:
Subjects must meet all of the following to be eligible for participation in the study:
1. Healthy adult male or female, ≥18 years of age,
2. Willing and able to give informed consent prior to study enrollment,
3. Able to comply with study requirements, and
4. Women of childbearing potential must have a negative urine pregnancy test prior to each vaccination, will be advised through the Informed Consent process to avoid becoming pregnant over the duration of the study, and must assert that they will employ an effective form of birth control for the duration of the study. Acceptable forms of birth control are: credible history of continuous abstinence from heterosexual activity or prior surgical sterilization, hormonal contraceptives (oral, injectable, implant, patch, ring), barrier contraceptives (condom or diaphragm), and intrauterine device (IUD). Women with an adequately documented history of surgical sterility, or ≥50 years of age and without menses for ≥ 1 year are exempt from urine pregnancy testing.

Exclusion Criteria:
Subjects meeting any of the following criteria are not eligible for participation in the study.

1. Any ongoing, symptomatic acute or chronic illness requiring medical or surgical care.
2. Asymptomatic conditions or findings (e.g., mild hypertension, dyslipidemia) that are not associated with evidence of end-organ damage are not exclusionary provided that they are being appropriately managed.
and are clinically stable (i.e., unlikely to result in symptomatic illness within the time-course of this study) in the opinion of the investigator.

Note that illnesses or conditions may be exclusionary, even if otherwise stable, due to therapies used to treat them (see exclusion criteria 2, 5, 7, 8).

2. Participation in research involving investigational product (drug / biologic / device) within 45 days before planned date of first vaccination.
3. History of a serious reaction to prior influenza vaccination.
4. History of Guillain-Barré Syndrome (GBS) within 6 weeks following a previous influenza vaccine.
5. Received any vaccine in the 4 weeks preceding the study vaccination; or any A(H7N9) avian influenza vaccine at any time.
6. Any known or suspected immunosuppressive condition, acquired or congenital, as determined by history and/or physical examination.
7. Chronic administration (defined as more than 14 continuous days) of immunosuppressants or other immune-modifying drugs within 6 months prior to the administration of the study vaccine. An immunosuppressant dose of glucocorticoid will be defined as a systemic dose ≥10 mg of prednisone per day or equivalent. The use of topical, inhaled, and nasal glucocorticoids will be permitted.
8. Administration of immunoglobulins and/or any blood products within the 3 months preceding the administration of the study vaccine or during the study.
9. Acute disease at the time of enrollment (defined as the presence of a moderate or severe illness with or without fever, or an oral temperature >38.0°C on the planned day of vaccine administration).
10. Known disturbance of coagulation.
11. Women who are pregnant or breastfeeding, or plan to become pregnant during the study.
12. Suspicion or recent history (within one year of planned vaccination) of alcohol or other substance abuse.
13. Any condition that in the opinion of the investigator would pose a health risk to the subject if enrolled or could interfere with evaluation of the vaccine or interpretation of study results (including neurologic or psychiatric conditions deemed likely to impair the quality of safety reporting).
14. Persons employed in a capacity that involves handling poultry or wild birds.

Clinical Endpoints Assessed:

Safety assessments: Assessment of Safety [ Time Frame: Day 0 to Day 384 ]
Number (and percentages) of subjects with solicited local and systemic AEs over the seven days post-injection and all adverse events, solicited and unsolicited, including adverse changes in clinical laboratory parameters, over 35 days post-first injection.

Significant New Medical Conditions, Medically Attended Events and Serious Adverse Events will be collected for one year post-second injection.

Immunogenicity assessments: Immunogenicity as assessed by hemagglutination-inhibiting (HAI) antibody titers against the vaccine-homologous A/Anhui/1/13 (H7N9) virus. [ Time Frame: Day 0 to Day 384 ]
- Geometric mean titer (GMT)
- Geometric mean ratio (GMR)
- Seroconversion rate (SCR)
- Seroresponse rate (SRR)

Results: Not yet available

Safety:

Immunogenicity
GMTs:

GMT Ratios (post:pre):

Per cent responding (4 fold or greater rise and definition for reporting):

Per cent responders at specified titre:

Others assays:

**Status of trial (ongoing/completed)**: Ongoing