Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial**: Dose-finding Study of Four Dosage Levels of an H7N9 Influenza Vaccine in Adults Between Ages of 18 Years and 65 Years

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov)**: NCT01928472

**Authors/sponsors**:

**Study Design**: Phase I Multi-center, Observer-Blind, Randomized Dose-Ranging Study of Adjuvanted and Non-Adjuvanted Cell Culture-Derived, Inactivated A/H7N9 Monovalent Subunit Influenza Virus Vaccine (H7N9c) in Adults 18 to <65 Years

**Objective**: Evaluate the safety and immunogenicity of four different doses of H7N9 vaccination in adults between the ages of 18 years and 65 years.

**Vaccine**:

- **Manufacturer**: Novartis
- **Type**: H7N9 (whole virus/subvirion/subunit/live/recombinant/DNA/vector): Inactivated subunit
- **Adjuvant**: MF59
- **Delivery system/site**: Intramuscularly

**Doses (antigen and adjuvant)**: low, mediu and high doses (no defined)

**Study population**: 400 adults

**Age range**: 18 to <65 Years  
**Health status**: healthy volunteers

**Specific inclusion/exclusion criteria**:

**Inclusion Criteria**:
1. Healthy adult subject ages 18-64 years,
2. Individuals willing to provide written informed consent
3. Individuals in good health.
4. Individuals who can comply with study procedures and follow-up.

**Exclusion Criteria**:
1. Individuals with history of cognitive or behavioral impairment or psychiatric disease,
2. Individuals unable to understand and follow study procedures,
3. History of significant illness,
4. History of chronic medical condition or progressive disease,
5. Allergy to any vaccine component or adverse event related to a vaccine component,
6. Impairment/alteration of the immune system,
7. Presence of progressive or severe neurological disorder,
8. Pregnant or breast-feeding,
9. Female of Child-bearing potential unwilling to use acceptable method of birth control,
10. Presence of medically significant cancer,
11. Receipt of investigational product within 30 day prior to entry into the study,
12. History of previous or suspected illness from avian flu caused by H7N9 virus,
13. History of H7 vaccination,
14. Body temperature of greater than or equal to 38.0°C (100.4°F) and/or acute illness within 3
days of intended study vaccination,
15. Receipt of any flu vaccination 2 weeks before study entry or 4 weeks after study vaccination,
16. Receipt of any vaccination 2 weeks before study entry or 4 weeks after study vaccination,
17. History of drug or alcohol abuse within the past 2 years,
18. Body Mass Index (BMI) greater than or equal to 35 kg/m²,
19. Individuals conducting the study or their immediate family members.

Clinical Endpoints Assessed:

Safety assessments:

• Percentage of subjects with solicited local adverse events
  To evaluate the safety and tolerability of each H7N9 vaccine group.

• Percentage of subjects with solicited systematic adverse events
  To evaluate the safety and tolerability of each H7N9 vaccine group.

• Percentage of subjects with unsolicited adverse events and percentage of subjects with serious
  adverse events
  To evaluate the safety and tolerability of each H7N9 vaccine group.

Immunogenicity assessments: Geometric Mean Titre (GMT), Geometric Mean Ration (GMR)
and percentage of subjects achieving seroconversion [ Time Frame: Day 1 and 43 ] [ Designated
as safety issue: No ]
To evaluate hemagglutination inhibition (HI) assay results for each H7N9 vaccine group after 2
vaccine doses, with descriptive summaries of the endpoints for Day 43.

Results:
Safety: Not yet available

Immunogenicity Not yet available

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