Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Evaluating the Safety and Immune Response to a Live H7N9 Influenza Virus Vaccine Followed by an Inactivated H7N9 Influenza Virus Vaccine, Given at Varying Intervals

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** NCT02151344

**Authors/sponsors:** Kawsar Talaat, John Hopkins Bloomberg School of Public Health/ National Institute of Allergy and Infectious Diseases (NIAID)

**Study Design:** Non-Randomized, Parallel Assignment, Open Label

**Vaccine:** H7N9, Strain A/Anhui/13 ca

**Manufacturer:** Medimmune

**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Live attenuated influenza vaccine

**Adjuvant:** None

**Delivery system/site:** Intranasal application

**Dose of antigen:** $10^7$ FFU/dose

**Experimental:** Cohort 1

Participants will receive one dose of the H7N9 A/Anhui/13 ca influenza virus vaccine at Day 0 and one dose at Day 28. They will then receive one dose of the inactivated subvirion H7N9 vaccine 1 month later.

**Experimental:** Cohort 2

Participants will receive one dose of the H7N9 A/Anhui/13 ca influenza virus vaccine at Day 0 and one dose at Day 28. They will then receive one dose of the inactivated subvirion H7N9 vaccine 2 months later.

**Experimental:** Cohort 3

Participants will receive one dose of the H7N9 A/Anhui/13 ca influenza virus vaccine at Day 0. They will then receive one dose of the inactivated subvirion H7N9 vaccine 2 months later.

**Experimental:** Cohort 4

Participants will receive one dose of the H7N9 A/Anhui/13 ca influenza virus vaccine at Day 0. They will then receive one dose of the inactivated subvirion H7N9 vaccine 1 month later.

**Experimental:** Cohort 5

Participants will receive one dose of the inactivated subvirion H7N9 vaccine at Day 0 and one dose at Day 28.

**Study population:** 100 volunteers of 18-49 years

**Age range:** Healthy

**Specific inclusion criteria:**

- Adult males and non-pregnant females between 18 years and 49 years of age, inclusive.
- Children will not be recruited or enrolled in this study because they are not in the apparent risk group, for safety considerations, and because of the need for isolation.
- General good health, without significant medical illness, physical examination findings, or significant laboratory abnormalities as determined by the investigator
- Agree to storage of blood specimens for future research
- Available for the duration of the trial
- Willingness to participate in the study as evidenced by signing the informed consent document
Clinical Endpoints Assessed:

Safety assessments:
• Frequency of vaccine-related reactogenicity events (REs) for 2 doses of pLAIV vaccine followed by a single dose of inactivated pIIV and compare to 2 doses of pIIV alone [ Time Frame: Measured through participants' last study visit: 90 days after receiving the last vaccine (Cohorts 1-4) or Day 118 (Cohort 5) ]
• Frequency of other adverse events (AEs) for 2 doses of pLAIV vaccine followed by a single dose of inactivated pIIV and compare to 2 doses of pIIV alone [ Time Frame: Measured through participants' last study visit: 90 days after receiving the last vaccine (Cohorts 1-4) or Day 118 (Cohort 5) ] [ Designated as safety issue: Yes ]

Immunogenicity assessments:
Measurement of the ability of the pLAIV vaccine to induce priming by assessing the response to a subsequent dose of pIIV [ Time Frame: Measured through participants' last study visit: 90 days after receiving the last vaccine (Cohorts 1-4) or Day 118 (Cohort 5) ]
• Measurement of the optimal interval between the priming with pLAIV and the subsequent boost with pIIV [ Time Frame: Measured through participants' last study visit: 90 days after receiving the last vaccine (Cohorts 1-4) or Day 118 (Cohort 5) ]
• Determination of whether 1 dose or 2 doses of pLAIV followed by a pIIV boost is sufficient to induce an optimal immune response [ Time Frame: Measured through participants' last study visit: 90 days after receiving the last vaccine (Cohorts 1-4) or Day 118 (Cohort 5) ]

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 tite :

Others assays:

Status of trial (ongoing/completed): May 2014 – February 2015 (ongoing)