Pandemic Influenza Vaccine Clinical Trial Abstract Minimum information:

**Title of Trial:** Double blind randomized study involving 24 participants with the main objective of assessing safety-tolerability and immune response of the newly manufactured LAIV

**Clinical Trial registration site if applicable (e.g. ClinicalTrials.gov):** Authors/sponsors: Dr Punnee Pitisuttithum/Thai Health & World Health Organization

**Study Design (including the phase of clinical trial):** Phase I/II

**Vaccine subtype:** HINI pandemic  
**Virus:** A/17/CA/2009/38  
**Manufacturer:** Government Pharmaceutical Organisation, Thailand  
**Type (whole virus/subvirion/subunit/live/recombinant/DNA/vector):** Live attenuated vaccine  
**Adjuvant:** None  
**Delivery system/site:** Intranasal administration  
**Doses (antigen and adjuvant, number of doses, intervals between administrations):** Part A: Two doses containing 10^5.8 EID/50 and 10^6.9 EID/50 per dose, two applications at day 0 and 21  
Part B: 10^7 EID50 per dose

**Study population**  
**Number of subjects involved:** Part A: 24 persons range: 18 – 49 years  
Part B: 324 Age range: 12-60  
**Health status:** Heath volunteers  
**Special inclusion/exclusion criteria:** Inclusion Criteria

- Healthy  
- Age 18-49 years old  
- Having Thai ID card or equivalent  
- Are seronegative to the specific H1N1 influenza virus determined by antibody titer less than 1:10 by HAI test to the corresponding antigen.  
- Anti HIV – Negative  
- All hematology & biochemistry within normal range  
- Able to read and write and sign written informed consent.

**1.2 Exclusion Criteria**

- Known history of egg allergy  
- Having had recently influenza infection confirmed as H1N1  
- History of bronchial asthma  
- History of chronic lung diseases  
- History of chronic rhinitis  
- History of immunodeficiency state  
- History of immunosuppression  
- Acute infectious and noninfectious diseases (within 2 weeks)  
- Exacerbation of chronic diseases or cancer or HIV positives  
- Anamnestic leukocytosis, hepatitis B and C positives  
- The volunteers who have been taking immunoglobulin products or have had a blood transfusion during past three months before the beginning of the experiment  
- Participation in other research study  
- Pregnancy or plan to become pregnant for 60 days after enrollment or breast feeding  
- Any concomitant medication with Aspirin

**Clinical Endpoints:**
Safety assessments: Assessed Daily history and Physical examination for 7, 21, 42, 60 days after first immunization

Immunogenicity assessments:
immunoassay type
HI (type of RBC used): Goose RBC
NT (type of neutralization assay): Microneutralization

Results

Safety:

Reactogenicity:
No fever reported in the low dose group. However one had fever of 38.2°C in the low dose. Few reported mild headache, fatigue and diarrhea and more so in the higher dose group.

AEs:

<table>
<thead>
<tr>
<th>Events</th>
<th>ALL</th>
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<tbody>
<tr>
<td>Experienced AE*</td>
<td>33 (137.5%)</td>
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<tr>
<td>Experienced AE suspected to be related to treatment**</td>
<td>8 (24.24%)</td>
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SAEs: one with the diagnosis of suspected pulmonary tuberculosis/ 

Immunogenicity

HI
Per cent responding (4 fold increase): one out of 9 in low dose group and none in the high dose group

\[ \text{HI} \geq 40 \]
\[ 5\% \]

NT:
\[ 5\% \]

Current status of the clinical trial (completed, ongoing, in preparation):
Part A: Completed.
Part B: Screening started in April 19, 2010

Date envisaged for availability of results, if not yet available: Part B study: immunization will start in early May 2010

Planned time schedule for next phase of development: to complete part B in August 2010.