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Safety of an Inactivated Influenza A (H1N1) 2009 Monovalent Vaccine (H1N1 vaccine) in HIV-1 Infected Pregnant Women.

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Abstract

Background: Pandemic H1N1 influenza poses increased risk in certain populations, such as HIV+ pregnant women. This report describes a phase II study of the safety and immunogenicity of H1N1 vaccine in HIV+ pregnant women.

Methods: 130 HIV+ pregnant women between 14-35 weeks gestation from 31 domestic sites enrolled between 10/8-11/13/09 and received 2 doses of Novartis inactivated H1N1 vaccine (30mcg/dose; 2 injections of 15mcg, separated by 21-28 days). All subjects had to be receiving HAART prior to/at enrollment. Safety and immunogenicity assessments were done after each dose, at delivery, and 3 and 6 months post delivery. All doses were administered by 12/14/09.

Results: Baseline demographics: Race: 56% Black, 8% White; Medians (ranges): Age: 29 (18-38) yrs; gestational age: 26 (14-34) weeks; CD4%: 31% (1-53%): RNA viral load: 75 copies/ml (40-294,000). 94% received two doses of vaccine. Eight of 28 deliveries to date were premature, while 78% of the study population continue to be pregnant. There was 1 fetal demise at week 21 of gestation, judged not related to study vaccine. There have been no occurrences of Guillain-Barré Syndrome or any ≥Grade 3 vaccine-related adverse events. There have been 4 patients with documented influenza A infections, all of whom recovered.

Conclusions: Administration of two 30mcg doses of H1N1 vaccine, was safe and demonstrated good short-term safety in HIV+ pregnant women. The rate of premature delivery continues to be monitored. Immunogenicity and long term safety will be assessed.

Objectives

1. **To assess the safety after each of two doses of inactivated swine-origin H1N1 influenza vaccine in HIV-1 infected pregnant women**
2. **To assess the antibody response after each of two doses of inactivated swine-origin H1N1 influenza vaccine in HIV-1 infected pregnant women**

Data presented here as of 2/4/2010

Methods

Regimen: The initial dose of inactivated swine-origin H1N1 influenza vaccine was administered to all eligible subjects during the study entry visit (Day 0) as a 30mcg dose(given as two 15mcg intramuscular injections). The second 30mcg dose of inactivated swine-origin H1N1 influenza vaccine (given as two 15mcg IM injections) was administered at Day 21 (+ 7 days).

Study Duration: Subjects will continue on study until they are 6 months post delivery

STUDY COMPLETED ENROLLMENT IN 6 WEEKS

Evaluable: Evaluable mother-infant pairs are defined as having received two doses of swine-origin H1N1 influenza vaccine and had a complete set of samples for immunogenicity laboratory assays obtained prior to delivery as per protocol.

Results: Demographics, N=130, Median (range)

- **Ethnicity: N=128 with non missing data**

White, Non Hispanic:	**8%**
Black, Non Hispanic:	**56%**
Hispanic, regardless of Race:	**34%**
Asian:	**1%**
Other:	**1%**

- **Maternal age: 28 years (18-38)**
- **Gestational age in weeks: 26 weeks (14-34)**
- **CD4 count: 472 (28-1382) N=126**
- **CD4%: 31% (1-53%)**
- **RNA copy: 77 (40-292,200) N=122**
- **Log 10 RNA: 1.9 (1.6-5.5) N=122**

Vaccination and Delivery Results

- 130 Subjects enrolled from 31 domestic sites
- 124/130 (95%) received 2 vaccines; 4/130 (3%) received one vaccine and 2/130 (1.5%) did not receive any vaccine at all
- 103 evaluable subjects
  - ➢No apparent differences between evaluable and non-evaluable women
- 67 delivered to date
  - ➢12 delivered premature (<37 weeks)
- 1 fetal demise at 21 weeks

Safety Results ≥Grade 3

- NONE judged vaccine related:
  - ➢Chemistry: 1
  - ➢Cardiovascular dysfunction: 1
  - ➢Dysuria: 1
  - ➢Headache: 3
  - ➢Vaginal discharge: 1
  - ➢Numbness: 1
- No episodes of Guillain-Barré Syndrome

Conclusions

- IMPAACT sites and system were able to develop this time critical study in a timely fashion
- Study was able to enroll quickly
- Administration of 2 doses of a high titer novel H1N1 vaccine was safe in HIV+ pregnant women
- No events of Guillain-Barré syndrome were noted
- Premature deliveries will continue to be monitored as 60 women had not yet delivered as of Feb. 4, 2010

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