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<http://www.wrairclinicaltrials.com>

Study Title: Phase 1a Study of Pandemic Swine Influenza A Hemagglutinin Monomer Vaccine

Physician in charge of the study: Dr. James Cummings

Study Location: Clinical Trials Center, WRAIR, 503 Robert Grant Ave, Silver Spring, MD 20910

Study Contact information: site staff at [www.ARMY CLINICALTRIALS.com](http://www.ARMY.CLINICALTRIALS.com), 301-319-9335

Purpose of the study: The main purpose of this study is to test the safety of a new influenza (flu) vaccine called HAC1. This vaccine may help protect people from the H1N1 or swine flu virus. This is the first time this particular vaccine will be given to people. There is currently an approved vaccine for the H1N1 (“swine”) flu. However, there may be some drawbacks to producing the vaccine; such as number of doses or if changes to the ingredients are needed rapidly. Current technology limits the amount of vaccine that may be made, which in turn, can lead to decreased availability when needed.

To participate in this study you must be:

- Between the ages of 18 and 50
- Healthy
- Not pregnant or lactating and willing to use reliable contraception for the duration of the study

You cannot participate in this study if you have:

- Received any vaccine (including seasonal influenza immunization) within the 30 days before the first dose of study vaccine, or have a high flu titer
- Donated or received any blood products in the last 3 months or plan to receive them during the study
- Human immunodeficiency virus (HIV), hepatitis B or hepatitis C virus infection
- Have certain medical conditions or take certain medications

Study Duration: The total time volunteers must be available is 10months; 3 months for screening and approximately 7 months for vaccination and follow-up.

Background Information:

The flu is a common infection caused by influenza viruses. The flu can cause mild to severe illness, with symptoms such as fever, chills, fatigue, cough, runny or stuffy nose, body aches, nausea and vomiting. Certain people at high risk, such as the very young or elderly, or those with chronic illnesses or are immunocompromised (such as those with cancer or HIV) may have serious complications, which can lead to death. Flu vaccines have been used safely and effectively to prevent, or decrease symptoms, for many years.



Last year (2009), a new and very different flu virus began spreading among people called the H1N1 flu (sometimes called the “swine flu”). This particular virus may cause either a greater number of people to become ill, or the illness may be more severe than usual. Worldwide there have been over 480,000 cases of H1N1. There is currently an approved vaccine for the H1N1 (“swine”) flu. However, there may be some drawbacks to producing the vaccine; such as number of doses or if changes to the ingredients are needed rapidly.

The vaccine being tested in this study is made in a new way, using tobacco plants and bacteria. The main purpose of the study is to find out if this new flu vaccine against the H1N1 flu, called HAC1 vaccine for short, is safe and effective when given to people.

The vaccine may be formulated with an adjuvant. An adjuvant is used to stimulate the body’s immune system, which may make the vaccine work better. The adjuvant used in this study has been given safely to people before.

Study Information: There will be a total of 80 volunteers in this study. All volunteers will be screened to make sure it is safe for them to participate. Screening involves a physical exam, collection of blood, a pregnancy test, and a medical history evaluation. Volunteers who can participate will be divided in 8 groups of 10 people as shown below:

- Group 1 Low dose HAC1 vaccine with no adjuvant
- Group 2 Low dose HAC1 vaccine with adjuvant
- Group 3 Medium dose HAC1 vaccine with no adjuvant
- Group 4 Medium dose HAC1 vaccine with adjuvant
- Group 5 High dose HAC1 vaccine with no adjuvant
- Group 6 High dose HAC1 vaccine with adjuvant
- Group 7 Placebo (a saline injection to compare reactions, no vaccine or adjuvant)
- Group 8 FDA approved monovalent influenza H1N1 vaccine(not the experimental vaccine this study is testing) and placebo (for 2nd injection)

This is a dose escalation study, which means we will vaccinate the low dose first followed by the medium and high dose groups. Each group will receive 2 doses of vaccine or placebo given about 21 days apart.

Follow-up visits involve a brief physical exam, collection of blood, and a review of any symptoms that occurred.

A brief schedule is below:

1. Pre-vaccination blood draw
2. Dose 1 (lower doses will be vaccinated first)
3. Five follow up visits 1, 2, 3, 7, and 14 days after receiving the vaccine



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4. Pre-vaccination blood draw
5. Dose 2, 21 days after the first dose
6. Five follow-up visits 1, 2, 3, 7, and 14 days after receiving the second dose of vaccine
7. Three additional follow-up visits

Compensation: Volunteers will be financially compensated for their time and effort.