# Swine Flu (Novel Influenza A H1N1) Vaccine Study

Submission date 23/09/2009	<b>Recruitment status</b> No longer recruiting		
Registration date	Overall study status		

24/09/2009

**Overall study status** Completed

Last EditedCondition category09/02/2011Infections and Infestations

[X] Prospectively registered

[\_] Protocol

[] Statistical analysis plan

[X] Results

[] Individual participant data

#### Plain English summary of protocol

Not provided at time of registration

#### Study website http://www.swineflutrial.org/

## **Contact information**

**Type(s)** Scientific

**Contact name** Prof Andrew Pollard

#### Contact details

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## Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

#### Secondary identifying numbers

HTA 09/94/01; 2009/08 H1N1

## Study information

#### Scientific Title

Open label, randomised, parallel-group, multi-centre study to evaluate the safety, tolerability and immunogenicity of Baxter H1N1 vaccine and GlaxoSmithKline H1N1 vaccine in children 6 months to 12 years of age

#### **Study objectives**

In the first half of this year a novel Influenza A H1N1 virus has resulted in an influenza pandemic. The United Kingdom has seen a particularly high incidence of disease. The highest rates of disease are being seen in young children. In anticipation of an influenza pandemic two vaccine manufacturers, Baxter and GlaxoSmithKline, have gained marketing authorisation approval from the European Medicines Agency (EMEA) for a pandemic strain vaccine under the "mockup" dossier route based on limited clinical trial data for a candidate H5N1 vaccine. This "mockup" dossier route for pandemic influenza vaccines allows the submission of a core pandemic dossier during the interpandemic period, which results in the approval of a mockup pandemic vaccine. This is followed by a fast track approval of the pandemic vaccine based on the submission of the pandemic variation when the situation arises. The Baxter and GlaxoSmithKline vaccines have now been modified to cover the novel influenza A H1N1 strain.

Given the high rates of swine flu disease in children, this age group is likely to particularly benefit from immunisation against this virus, however there are few data on the use of these vaccines in a paediatric population. The proposed study therefore aims to assess the immunogenicity, safety, and tolerability of these two H1N1 vaccines when administered as two doses three weeks apart to children aged 6 months to 12 years of age.

#### **Ethics approval required** Old ethics approval format

**Ethics approval(s)** Oxford Research Ethics Committee A, approved on 18/09/2009 (ref: 09/18/2009)

**Study design** Phase II open-label randomised parallel-group multicentre trial

**Primary study design** Interventional

**Secondary study design** Randomised controlled trial

**Study setting(s)** Not specified

Study type(s)

#### Prevention

#### Participant information sheet

Patient information can be found at: http://www.swineflutrial.org/swineflu\_screen. html#information

#### Health condition(s) or problem(s) studied

Influenza

#### Interventions

Baxter Novel Influenza A H1N1 Whole Virus Vaccine. Other Name: Celvapan® Two 0.5 ml doses of vaccine given within 3 weeks interval given intramuscularly

GlaxoSmithKline Novel Influenza A H1N1 Split Virion Vaccine. Other Name: Pandemrix® Two 0.25 ml doses of vaccine given within 3 weeks interval given intramuscularly.

Follow up period: 3 weeks after second vaccine dose

#### Intervention Type

Drug

#### Phase

Phase II

#### Drug/device/biological/vaccine name(s)

Baxter Influenza A H1N1 Whole Virus Vaccine (Celvapan®), GlaxoSmithKline Influenza A H1N1 Split Virion Vaccine (Pandemrix®)

#### Primary outcome measure

1. Percentage of subjects with a 4 fold rise in microneutralisation (MN) titre between the prevaccination sample and sample taken 3 weeks after the second dose

2. Percentage of participants experiencing each of fever (>=38°C per axilla), local tenderness, local swelling or local erythema within the 7 days following each immunisation with the study vaccines

#### Secondary outcome measures

1. Percentage of subjects with an HAI titre >=1 in 32, assessed 3 weeks after completion of a two dose course of vaccination

2. Percentage of subjects with a 4 fold rise in HAI titre between the pre-vaccination sample and sample taken 3 weeks after the second dose

3. The geometric mean fold rises in HAI titres from baseline to after 3 weeks after 2 doses of the Baxter H1N1 vaccine and the GSK H1N1 vaccine

4. The geometric mean fold rises in MN titres from baseline to 3 weeks after 2 doses of the Baxter H1N1 vaccine and the GSK H1N1 vaccine

5. The geometric mean HAI and MN titres 3 weeks after 2 doses of the Baxter H1N1 vaccine and the GSK H1N1 vaccine

6. Percentage of participants experiencing each of: reduced feeding, reduced activity, irritability, persistent crying, vomiting or diarrhoea, receiving medication for pain or temperature (6 month to 5 year olds)

7. Percentage of participants experiencing each of: malaise, headache, nausea/ vomiting, diarrhoea, reduced appetite, muscle pain or joint pain, receiving analgesic/ antipyretic

#### medication (5 to 12 year olds)

8. The effect of genetic polymorphisms on the immunogenicity and reactogenicity of the H1N1 vaccines

#### Overall study start date

26/09/2009

#### **Completion date**

27/09/2010

## Eligibility

#### Key inclusion criteria

1. Baby or child (both males and females) aged between 6 months to 12 years of age (i.e., to day before 13th birthday)

2. For whom a parent/legal guardian has given written informed consent after the nature of the study has been explained

3. Available for all the visits scheduled in the study

4. Willingness to complete all study procedures

Participant type(s)

Patient

**Age group** Child

**Lower age limit** 6 Months

#### Upper age limit

12 Years

Sex

Both

#### Target number of participants

1,000

#### Key exclusion criteria

1. History of any vaccine against novel influenza A strain H1N1 (based on verbal confirmation from parent/guardian)

2. Previous laboratory confirmed case of novel influenza A strain H1N1 or treatment with oseltamivir or zanamivir for novel influenza A strain H1N1 (n.b. a child commenced on treatment with oseltamivir or zanamivir for novel influenza A strain H1N1 whose treatment was stopped following negative microbiological tests for H1N1 on nasal swabs would be allowed to enrol in the study)

3. History of severe allergic reaction after previous vaccinations or hypersensitivity to any H1N1 vaccine component

4. Current egg allergy

5. Known or suspected impairment/alteration of the immune system

6. Disorders of coagulation

7. Immunosuppressive therapy, use of systemic corticosteroids for more than 1 week within the 3 months prior to enrolment

8. Receipt of blood, blood products and/or plasma derivatives or any immunoglobulin preparation within 3 months prior to enrolment

9. Intent to immunise with any other vaccine(s) against novel influenza A strain H1N1 throughout the study period

10. Participation in another clinical trial of an investigational medical product

11. Any condition which, in the opinion of the investigator, might interfere with the evaluation of the study objectives. Children with chronic, stable medical illnesses that do not result in immunosuppression (e.g., cerebral palsy, epilepsy, cystic fibrosis, congenital heart disease) will be allowed to participate in the study, unless these conditions will in some way interfere with the completion of study procedures. Children with conditions that may alter the immune response to vaccines (e.g., Trisomy 21) or will affect the ability to accurately describe adverse events (e.g., children over 5 years of age but with severe learning difficulties) will be excluded

#### Date of first enrolment

26/09/2009

### Date of final enrolment

27/09/2010

### Locations

**Countries of recruitment** England

United Kingdom

#### **Study participating centre Oxford Vaccine Group** Oxford United Kingdom OX3 7LJ

### Sponsor information

**Organisation** University of Oxford (UK)

#### Sponsor details

c/o Heather House Clinical Trials and Research Governance Office Manor House Oxford England United Kingdom OX3 9DU

**Sponsor type** University/education

Website http://www.ox.ac.uk/

ROR https://ror.org/052gg0110

## Funder(s)

**Funder type** Government

**Funder Name** NIHR Health Technology Assessment Programme - HTA (UK) - HTA Clinical Evaluation and Trials

### **Results and Publications**

#### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	27/05/2010		Yes	No
<u>Results article</u>	results	01/10/2010		Yes	No