

# Swine Flu (Novel Influenza A H1N1) Vaccine Study

<b>Submission date</b> 23/09/2009	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 24/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 09/02/2011	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00980850

**Protocol serial number**  
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 (EMA) 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)

## **Primary study design**

Interventional

## **Study design**

Phase II open-label randomised parallel-group multicentre trial

## **Study type(s)**

Prevention

## **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(s)**

1. Percentage of subjects with a 4 fold rise in microneutralisation (MN) titre between the pre-vaccination sample and sample taken 3 weeks after the second dose
2. Percentage of participants experiencing each of fever ( $\geq 38^{\circ}\text{C}$  per axilla), local tenderness, local swelling or local erythema within the 7 days following each immunisation with the study vaccines

## **Key secondary outcome(s)**

1. Percentage of subjects with an HAI titre  $\geq 1$  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

## **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

**Healthy volunteers allowed**

No

**Age group**

Child

**Lower age limit**

6 Months

**Upper age limit**

12 Years

**Sex**

All

**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

United Kingdom

England

### Study participating centre

Oxford Vaccine Group

Oxford

United Kingdom

OX3 7LJ

## Sponsor information

### Organisation

University of Oxford (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

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type

Details  
results

Date created Date added Peer reviewed? Patient-facing?

<a href="#">Results article</a>		27/05/2010		Yes	No
<a href="#">Results article</a>	results	01/10/2010		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes