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Swine Flu (Novel Influenza A H1N1) Vaccine Study

Submission date	Recruitment status	[X] Prospectively registered
23/09/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
09/02/2011	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

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

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

NCT00980850

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 pre-vaccination 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
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Manor House
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England

United Kingdom
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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?
Results article	results	27/05/2010		Yes	No
Results article	results	01/10/2010		Yes	No