ISRCTN92328241 https://doi.org/10.1186/ISRCTN92328241

# Head to head study of influenza H1N1 vaccines in adults

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| **Submission date**<br>26/08/2009 | **Recruitment status**<br>No longer recruiting | [X] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[X] Results<br>[_] Individual participant data |
| **Registration date**<br>28/08/2009 | **Overall study status**<br>Completed | |
| **Last Edited**<br>16/05/2011 | **Condition category**<br>Infections and Infestations | |

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

## Contact information

**Type(s)**
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**
HTA 09/93/01

## Study information

**Scientific Title**

A randomised, partially observer-blind, multi-centre, head-to-head comparison of a two dose regimen of Baxter and GSK H1N1 pandemic vaccines, administered 21 days apart.

## Study objectives
Baxter cell-culture, non-adjuvanted, whole virus H1N1 vaccine, and GSK AS03-adjuvanted, split H1N1 vaccine both meet all three Committee of Human Medicinal Products (CHMP) criteria, either after one or two doses of vaccine

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
To be submitted as of 26 August 2009

## Study design
Multi-centre randomised comparative study

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Not specified

## Study type(s)
Prevention

## Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied
Pandemic H1N1 influenza 2009

## Interventions
Group 1: Two doses of Baxter H1N1 vaccine, given 21 days apart
Group 2: Two doses of GSK H1N1 vaccine, given 21 days apart

## Intervention Type
Drug

## Phase
Not Applicable

## Drug/device/biological/vaccine name(s)
H1N1 vaccines (Baxter and GSK vaccines)

## Primary outcome measure

1. The number of seroconversions or significant increase in haemagglutination inhibition (and microneutralisation) antibody titres
2. Mean geometric increase in haemagglutination inhibition (and microneutralisation) antibody titres
3. The proportion of subjects achieving an haemagglutination inhibition antibody titre of >40

These outcome measures are all part of the CPMP criteria and will be assessed in blood samples collected 21 days after the first and second doses of vaccine.

### Secondary outcome measures
1. The kinetics of the haemagglutination inhibition and microneutralisation antibody responses to vaccination
2. The persistence of haemagglutination inhibition and microneutralisation antibody responses 6 months after vaccination
3. The breadth of the antibody response to any antigenic variant that might emerge before the 2010-2011 influenza season

### Overall study start date
07/09/2009

### Completion date
07/03/2010

## Eligibility

### Key inclusion criteria
1. Mentally competent adults, who have signed an informed consent form after having received a detailed explanation of the study protocol
2. Clinically healthy, male or female volunteers aged 18 years of age and older, including the over 65's, and those with stable high-risk medical conditions. (NOTE: 'Stable' is defined as having no medical consultations for an exacerbation or worsening of any chronic medical condition during the preceding 8 weeks, AND have been maintained on a stable drug regimen for at least 2 weeks prior to study entry as assessed by the medical history)
3. Are able to understand and comply with all study procedures and to complete study diaries,
4. Individuals who can be contacted and are available for all study visits
5. Females should either be using secure contraceptive precautions including a) the oral contraceptive pill, b) condom/barrier contraception c) partner has had a vasectomy, d) be surgically sterilised, or e) post-menopausal (defined as at least two years since the last menstrual period)

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex

Both

## Target number of participants
360

## Key exclusion criteria
1. Subjects who are unable to lead an independent life either physically or mentally
2. Women should not be pregnant or lactating
3. Women who refuse to use a reliable contraceptive method Days 0 to 42 of the study
4. Confirmed H1N1 infection, as determined by laboratory tests
5. Have received oseltamivir or zanamivir for influenza-like illness since May 2009
6. Have a household member who had confirmed H1N1 infection, as determined by laboratory tests, and/or received oseltamivir or zanamivir for influenza-like illness since May 2009
7. Receipt of another investigational agent (vaccine or medicinal product) in the preceding 4 weeks
8. Unwilling to refuse participation in another study during Days 0 to 42 of the study
9. Any clinically significant concurrent illness or unstable medical condition including: malignant tumours, acute or progressive renal or hepatic pathology, chronic obstructive pulmonary disease requiring oxygen therapy, and any active neurological disorder
10. Individuals who have had acute respiratory pathology or infections requiring systemic antibiotic or antiviral therapy during the preceding 7 days (chronic antibiotic therapy for prevention of urinary tract infections is acceptable)
11. Subjects who had a temperature >38°C within 3 days of vaccination
12. Any acute illness at the time of vaccination. Note: minor infections without fever or systemic upset are not contraindications/exclusion criteria.
13. Subjects with known or suspected impairment/alteration of immune function, including:
13.1. receipt of oral immunosuppressive drugs or other drugs listed in section 8 of the British National Formulary (BNF) or chloroquine, gold or penicillamine or other drugs listed in section 10.1.3 of the BNF to suppress a chronic disease process, or have received in the last 6 months radiotherapy or chemotherapy (Note: long-term, inhaled steroids for asthma management is acceptable)
13.2. receipt of immunostimulants or interferon
13.3. receipt of an immunoglobulin preparation, blood products, and/or plasma derivatives within 3 months of the study
13.4. Anyone at high risk of developing immunocompromising condition
13.5. Received radiotherapy or chemotherapy during the 6 months preceding the study
14. Subjects for whom surgery is planned during Days 0 to 42 of the study
15. Regularly drink more than 40 units of alcohol weekly
16. Known or suspected drug abuse (recreational or prescribed)
17. Individuals who, in the opinion of the investigator, have conditions that might complicate interpretation of the study results
18. Subjects with hypersensitivity to eggs, chicken protein, chicken feathers, influenza viral protein, neomycin or kanamycin, products containing mercury, or any component of the study vaccines
19. Subjects with a history of any neurological symptoms and signs, or anaphylactic shock following administration of any vaccine
20. Actual or planned receipt of another vaccine, including seasonal influenza vaccine, during the period 3 weeks before to 3 weeks after vaccination on Days 0 and 21

## Date of first enrolment
07/09/2009

**Date of final enrolment**
07/03/2010

# Locations

**Countries of recruitment**
England

United Kingdom

**Study participating centre**
**Infectious Diseases Unit**
Leicester
United Kingdom
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# Sponsor information

**Organisation**
University Hospitals of Leicester NHS Trust (UK)

**Sponsor details**
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**Sponsor type**
Hospital/treatment centre

**Website**
http://www.uhl-tr.nhs.uk/

**ROR**
https://ror.org/02fha3693

# Funder(s)

**Funder type**
Government

**Funder Name**
NIHR Health Technology Assessment Programme - HTA (UK)

# 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 | 01/12/2010 | | Yes | No |