

Head to head study of influenza H1N1 vaccines in adults

Submission date 26/08/2009	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 28/08/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 16/05/2011	Condition category 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

Protocol serial number
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

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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 $>38^{\circ}\text{C}$ 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

United Kingdom

England

Study participating centre

Infectious Diseases Unit

Leicester
United Kingdom
LE1 5WW

Sponsor information

Organisation

University Hospitals of Leicester NHS Trust (UK)

ROR

<https://ror.org/02fha3693>

Funder(s)

Funder type

Government

Funder Name

NIHR Health Technology Assessment Programme - HTA (UK)

Results and Publications

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