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

Head to head study of influenza H1N1 vaccines in adults

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Karl Nicholson

Contact details
Infectious Diseases Unit
Leicester Royal Infirmary
Leicester
United Kingdom
LE1 5WW

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°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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes