

Broader Protection Against Pneumococcal Disease

Submission date 04/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/06/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 29/08/2013	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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
8092

Study information

Scientific Title

A follow-on, multicentre, open-label, clinical, phase IV trial to investigate the persistence of serotype-specific antibodies at 40 months of age in children who have received either the 7-valent or the 13-valent pneumococcal conjugate vaccine at 2, 4 and 12 months of age and

assessing the immunogenicity of a 13-valent pneumococcal conjugate vaccine booster dose given at 40 months of age

Study objectives

1. Investigating the persistence of serotype-specific antibodies at 40 months of age in children who have received either a 7-valent or 13-valent pneumococcal conjugate vaccine at 2, 4 and 12 months of age
2. Assessing the immunogenicity of a 13-valent pneumococcal conjugate vaccine booster dose at 40 months of age

Ethics approval required

Old ethics approval format

Ethics approval(s)

Oxfordshire REC C approved on the 18/03/2010 (ref: 10/H0606/9)

Study design

Non-randomised interventional prevention trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions

Study vaccine: 13-Valent Pneumococcal Conjugate Vaccine. Intramuscular administration on the deltoid area of the non-dominant arm at 40 months of age using a 23 gauge 25 mm needle.

This is an open study, so there will be one group only, non-blinded.

Following a blood test on visit 1, participants will receive one booster dose of the 13-valent pneumococcal conjugate vaccine, whatever vaccine they received in the parent study. This will be applied in the non-dominant arm, at a dose of 0.5 ml and as an intramuscular injection. Participants will be monitored for the next 4 days by their parents/legal guardians looking for local/general reactions. A further visit 4 weeks after vaccination will take place and a blood test will be done then. Pre-school booster vaccines will be offered and administered at this point if they had not received this through their local GP. The study will be finished after this visit. No further follow up will take place.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

7-valent pneumococcal conjugate vaccine, 13-valent pneumococcal conjugate vaccine

Primary outcome(s)

To assess the proportion of participants immunised with the 13-valent pneumococcal conjugate vaccine

Key secondary outcome(s)

1. The PCV13 serotype-specific IgG GMCs, OPA GMTs and proportion of participants with OPA titres = 1:8
2. Rates of local and systemic reactions following vaccination with pre-school PCV13 booster dose at 40
3. PCV13 serotype-specific IgG geometric mean concentrations (GMCs), opsonophagocytic activity (OPA)
4. Proportion of participants with PCV13 serotype-specific IgG concentrations = 0.35 mcg/ml at 40 months

Completion date

31/03/2011

Eligibility**Key inclusion criteria**

Participants must meet the following conditions in order to be enrolled:

1. Participant completed the Wyeth-sponsored PCV13 infant trial study (6096A1-007) at one of the study sites participating in this follow-on study
2. Aged 39 - 46 months (inclusive) at time of enrolment, either sex
3. Available for entire study period and whose parent/legal guardian can be reached by telephone
4. Healthy children as determined by medical history, physical examination, done by a study nurse (and/or study doctor if required, depending on the medical history of the participant and physical assessment), and judgment of the investigator
5. Parent/legal guardian must be able to complete all relevant study procedures during study participation

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

39 months

Upper age limit

46 months

Sex

All

Key exclusion criteria

Participants with any of the following conditions or characteristics will be excluded from study enrolment:

1. Has received further doses of pneumococcal vaccination with licensed or investigational pneumococcal vaccine other than those given as part of the Wyeth-sponsored PCV13 infant trial study (6096A1-007)
2. A previous anaphylactic reaction to any vaccine or vaccine-related component
3. Contraindication to vaccination with pneumococcal conjugate vaccine
4. Bleeding diathesis or condition associated with prolonged bleeding time that would contraindicate intramuscular injection
5. Known or suspected immune deficiency or suppression
6. History of culture-proven invasive disease caused by *S pneumoniae*
7. Major known congenital malformation or serious chronic disorder
8. Significant neurologic disorder or history of seizures including febrile seizure, or significant stable or evolving disorders such as cerebral palsy, encephalopathy, hydrocephalus, or other significant disorder
9. Receipt of blood products or gamma-globulin (including hepatitis B immunoglobulin and monoclonal antibodies, e.g., synagisB)
10. Participation in another investigational study other than the Wyeth-sponsored PCV13 infant trial study (6096A1-007). Participation in purely observational studies is acceptable.
11. Child who is a direct descendant (child, grandchild) of the study site personnel

Date of first enrolment

01/03/2010

Date of final enrolment

31/03/2011

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Oxford Vaccine Group, CCVTM

Oxford

United Kingdom

OX3 7LJ

Sponsor information

Organisation

John Radcliffe Hospital (UK)

ROR

<https://ror.org/0080acb59>

Funder(s)

Funder type

Industry

Funder Name

Wyeth Pharmaceuticals (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?
HRA research summary			28/06/2023	No	No