

# Broader Protection Against Pneumococcal Disease

**Submission date**

04/05/2010

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

11/06/2010

**Overall study status**

Completed

☐ Statistical analysis plan

☐ Results

**Last Edited**

29/08/2013

**Condition category**

Infections and Infestations

☐ Individual participant data

☐ Record updated in last year

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

Dr Florencia Tatangeli

**Contact details**

Oxford Vaccine Group, CCVTM  
Churchill Hospital  
Old Road  
Headington  
Oxford  
United Kingdom  
OX3 7LJ

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

## Secondary study design

Non randomised controlled trial

## Study setting(s)

GP practice

## 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

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 measure**

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

### **Secondary outcome measures**

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

### **Overall study start date**

01/03/2010

### **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

**Age group**

Child

**Lower age limit**

39 Months

**Upper age limit**

46 Months

**Sex**

Both

**Target number of participants**

Planned Sample Size: 100; UK Sample Size: 100

**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**

England

United Kingdom

**Study participating centre**

**Oxford Vaccine Group, CCVTM**

Oxford

United Kingdom

OX3 7LJ

## **Sponsor information**

**Organisation**

John Radcliffe Hospital (UK)

**Sponsor details**

Headley Way

Headington

Oxford

England

United Kingdom

OX3 9DU

**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.oxfordradcliffe.nhs.uk/aboutus/hospitals/jr.aspx>

**ROR**

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

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Wyeth Pharmaceuticals (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? |
|--------------------------------------|---------|--------------|------------|----------------|-----------------|
| <a href="#">HRA research summary</a> |         |              | 28/06/2023 | No             | No              |