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Broader Protection Against Pneumococcal Disease

Submission date	Recruitment status	[_] Prospectively registered
04/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
11/06/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
29/08/2013	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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 afer 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 gemoetric 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?
HRA research summary			28/06/2023	No	No