ISRCTN56766232 https://doi.org/10.1186/ISRCTN56766232

Pneumococcal vaccine (PCV10) study

Submission date	Recruitment status	[_] Prospectively registered
13/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2015	Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2009/04

Study information

Scientific Title
A randomised open-label immunogenicity study of the 10 Valent Pneumococcal vaccine (PCV10) given as part of the routine infant immunisation schedule to children in Kathmandu, Nepal

Acronym
PCV10

Study objectives
A 2+1 schedule of the 10 valent pneumococcal conjugate vaccine will provide a good serological response and that this will be non-inferior to a 3+0 schedule.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Oxford Tropical Research Ethics Committee (OxTREC) approved on the 4th December 2009 (ref: 61/09)
2. Nepal Health Research Council Ethics Committee approved on the 21st January 2010 (ref: 807)

Study design
Single-centre interventional unblinded randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Pneumococcus

Interventions
1. The proportion of participants with vaccine pneumococcal serotype-specific IgG antibody concentrations greater than or equal to 0.2 micrograms/mL at 18 weeks of age, 1 month following primary immunisation with PCV10 at 6, 10 and 14 weeks (3 + 0 group) and the proportion of participants with vaccine pneumococcal serotype-specific IgG antibody concentrations greater than or equal to 0.2 micrograms/mL at 18 weeks of age, 1 month following primary immunisation with PCV10 at 6 and 14 weeks of age (2 + 1 group) and to

demonstrate non-inferiority (within 10% levels) of the 2 + 1 group versus 3 + 0 group for this proportion for each of serotypes 1, 5 and 14.
2. The proportion of participants with vaccine pneumococcal serotype-specific IgG antibodies greater than or equal to 0.2 micrograms/mL at 18 weeks and 10 months of agefor each of the three study groups
3. The proportion of participants with vaccine pneumococcal serotype-specific opsonophagocytic activity greater than or equal to 8 at 18 weeks and 10 months of age for each of the three study groups
4. The vaccine pneumococcal serotype-specific geometric mean IgG antibody concentrations at 18 weeks and 10 months of age in infants in each of the three study groups
5. The vaccine pneumococcal serotype-specific geometric mean opsonophagocytic titres at 18 weeks and 10 months of age in infants in each of the three study groups
6. The proportion of participants in the 2+1 group with vaccine pneumococcal serotype-specific IgG antibody concentrations greater than or equal to 0.2 micrograms/mL prior to receiving a booster at 9 months of age
7. The proportion of participants in the 2+1 group with vaccine pneumococcal serotype opsonophagocytic activity titre greater than or equal to 8 prior to receiving a booster dose of PCV10 at 9 months of age
8. The vaccine pneumococcal serotype-specific geometric mean opsonophagocytic titres and geometric mean IgG antibody concentrations in infants in the 2+1 group prior to receiving a booster dose of PCV10 at 9 months of age
9. The nasopharyngeal pneumococcal serotype-specific carriage rates, at 9 months of age, following immunisation with a PCV10 i.e. post-dose 3 in 3+0 schedule, post-dose 2 in 2+1 schedule and those not receiving the pneumococcal vaccine
10. Protein D-specific IgG antibody geometric mean concentrations in infants in the control and 3+0 groups at the age of 18 weeks and 10 months and in the 2+1 group at the age of 18 weeks, 9 months and 10 months

Participants in the 3+0 and 2+1 groups will be followed until 10 months of age and those in the control group will be followed until 11 months of age.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
10 valent pneumococcal vaccine (PCV10)

Primary outcome measure
The proportion of participants with IgG antibodies against serotypes 1, 5 and 14 greater than or equal to 0.2 micrograms/mL 1 month post-dose 3 at age of 10 months after receiving PCV10 at 6 weeks, 14 weeks and 9 months (2 + 1 group).

Secondary outcome measures
1. The proportion of participants with vaccine pneumococcal serotype-specific IgG antibody concentrations greater than or equal to 0.2 micrograms/mL at 18 weeks of age, 1 month following primary immunisation with PCV10 at 6, 10 and 14 weeks (3 + 0 group) and the proportion of participants with vaccine pneumococcal serotype-specific IgG antibody concentrations greater than or equal to 0.2 micrograms/mL at 18 weeks of age, 1 month

following primary immunisation with PCV10 at 6 and 14 weeks of age (2 + 1 group) and to demonstrate non-inferiority (within 10% levels) of the 2 + 1 group versus 3 + 0 group for this proportion for each of serotypes 1, 5 and 14.
2. The proportion of participants with vaccine pneumococcal serotype-specific IgG antibodies greater than or equal to 0.2 micrograms/mL at 18 weeks and 10 months of agefor each of the three study groups
3. The proportion of participants with vaccine pneumococcal serotype-specific opsonophagocytic activity greater than or equal to 8 at 18 weeks and 10 months of age for each of the three study groups
4. The vaccine pneumococcal serotype-specific geometric mean IgG antibody concentrations at 18 weeks and 10 months of age in infants in each of the three study groups
5. The vaccine pneumococcal serotype-specific geometric mean opsonophagocytic titres at 18 weeks and 10 months of age in infants in each of the three study groups
6. The proportion of participants in the 2+1 group with vaccine pneumococcal serotype-specific IgG antibody concentrations greater than or equal to 0.2 micrograms/mL prior to receiving a booster at 9 months of age
7. The proportion of participants in the 2+1 group with vaccine pneumococcal serotype opsonophagocytic activity titre greater than or equal to 8 prior to receiving a booster dose of PCV10 at 9 months of age
8. The vaccine pneumococcal serotype-specific geometric mean opsonophagocytic titres and geometric mean IgG antibody concentrations in infants in the 2+1 group prior to receiving a booster dose of PCV10 at 9 months of age
9. The nasopharyngeal pneumococcal serotype-specific carriage rates, at 9 months of age, following immunisation with a PCV10 i.e. post-dose 3 in 3+0 schedule, post-dose 2 in 2+1 schedule and those not receiving the pneumococcal vaccine
10. Protein D-specific IgG antibody geometric mean concentrations in infants in the control and 3+0 groups at the age of 18 weeks and 10 months and in the 2+1 group at the age of 18 weeks, 9 months and 10 months

Overall study start date
02/05/2010

Completion date
31/10/2011

Eligibility

Key inclusion criteria
1. Parent/guardian of participant is willing and able to give informed consent for participation in the study
2. In good health as determined by:
2.1. Medical history
2.2. Physical examination
2.3. Clinical judgement of the investigator
3. Male or female, aged 40 - 60 days at time of first study vaccination
4. Participants residing in Kathmandu
5. Parents able (in the Investigators opinion) and willing to comply with all study requirements

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
40 Days

Upper age limit
60 Days

Sex
Both

Target number of participants
A total of 390 participants (3+0 group = 120; 2+1 group = 120; control group = 150)

Key exclusion criteria
1. Parent/guardian unwilling or unable to give written informed consent to participate in the study
2. Previous immunisation (excluding BCG and hepatitis B) or planned vaccination during the study period with vaccine not foreseen by this study protocol except influenza vaccine when locally recommended
3. Premature birth (less than 37 weeks gestation)
4. Previous hospital admission
5. Any other significant disease or disorder which, in the opinion of the Investigator, may either put the participants at risk because of participation in the study, or may influence the result of the study, or the participant's ability to participate in the study
6. Use of any investigational or non-registered product (drug or vaccine) within 30 days preceding the vaccination, or planned use during the study period
7. Concurrently participating in another clinical study, at any time during the study period, in which the participant has been or will be exposed to an investigational or a non-investigational product (pharmaceutical product or device)

Date of first enrolment
02/05/2010

Date of final enrolment
31/10/2011

Locations

Countries of recruitment
England

Nepal

United Kingdom

Study participating centre

University of Oxford
Oxford
United Kingdom
OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

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Sponsor type
University/education

Website
http://www.ox.ac.uk/

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
University of Oxford (UK)

Funder Name
GlaxoSmithKline (GSK) (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?
Results article	results	01/04/2015		Yes	No