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Evaluation of alternative vaccination schedules for Pneumococcal Conjugate Vaccine (PCV) (Philippines)

Submission date
04/08/2004

Recruitment status
No longer recruiting

Registration date
22/09/2004

Overall study status
Completed

Last Edited
06/07/2009

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
WHO/RPC032

Study information

Scientific Title

Study objectives
This study proposes evaluation of immunogenicity and safety of 1 to 3 doses of PCV or alternatively one or two doses of PCV. The vaccines are given within the schedule of the Expanded Programme on Immunisation (EPI) of 6, 10, and 14 weeks common in many developing countries. The proposed age for the first immunisation with PCV is 6 weeks of age, which has the highest coverage and best timeliness in most national programmes. Both PCV and PPS vaccines have been used as a booster following the primary series with PCV. The PPS vaccine with higher PS content (25 mcg vs. 2-10 mcg) may induce higher GMCs than PCV vaccines, but the avidity of antibodies might be higher following a booster dose of PCV. The results of this study together with information on disease burden estimates and cost-effectiveness analyses could play an important part in the decision-making process or whether or not to include the PCV in the national immunization program.

Objectives:
The primary objective of this study is to compare immune responses following the primary series of one or two doses of PCV to the reference group receiving three doses of PCV when measured at 18 weeks of age.

The secondary objectives are:
1. To describe the peak antibody responses one month after 1, 2 or 3 doses of PCV in early infancy
2. To compare the development of immunological memory by the 3 different immunisation schedules with PCV
3. To assess the immune response to serotypes 1 and 5 present in the PPS but not in the PCV in infants receiving PPS at 9 months of age
4. To describe persistence of serotype specific anti-pneumococcal PS antibodies following three different primary series schedules when measured at 9 months of age
5. To confirm the functional activity of the elicited antibodies by evaluating the opsonophagocytic activity of the antibodies in a randomly selected sub-set of 30 serum samples taken at 18 weeks and 7 days after the vaccinations at 9 months in each of the four study arms
6. To describe safety and tolerability of PCV administered according to the different immunisation schedules (combined active and passive surveillance)
7. To describe the immunogenicity of concomitant vaccine antigens (DT, HBV, Hib) at 18 weeks of age in order to rule out interference caused by PCV

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Primary study design
Interventional

Study design
Randomised controlled trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied

Pneumococcus/vaccines

Interventions
The study is a multi-centre, individual-randomised, open, proof of principle phase II trial to be carried out in Cabuyao, the Philippines with 4 arms. The study groups will receive 1, 2 or 3 doses of 7-valent pneumococcal conjugate vaccine (PCV), reference group will receive the standard 3-dose schedule of PCV and the control group no pneumococcal vaccines except at the exit from study. The effect of boosting at 9 months of age with pneumococcal polysaccharide vaccine after one or two doses of PCV on the antibody concentrations and B cell memory will be studied as well as the possible induction of hyporesponsiveness.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pneumococcal conjugate vaccine

Primary outcome(s)
Not provided at time of registration

Key secondary outcome(s)
Not provided at time of registration

Completion date
31/12/2006

Eligibility

Key inclusion criteria
Children who:
1. Are considered to be in good health on the basis of medical history and physical examination
2. Born at full term of pregnancy (≥37 weeks)
3. Are at least 6 weeks (max 9 weeks) of age when starting the Diphtheria, Tetanus, Pertussis (DTP)
4. Whose parents have lived in the study area at least 3 months and have no intention to move out of the area during the next 9 months
5. For whom at least one of the parents or other legally acceptable representative has given his /her informed consent attested by a signature

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Sex
All

Key exclusion criteria
Children who:
1. Have neurologic disease (an absolute contraindication to the DTP vaccine)
2. Have known or suspected impairment of immunological function
3. Have acute illness at the time of inclusion or have fever (rectal temperature ≥38°C)
4. Have already got their first DTP vaccine dose or first Hepatitis B Virus (HBV) dose, or first Haemophilus influenzae type b (Hib) dose
5. Have known or suspected history of severe atopy
6. Are enrolled or scheduled to be enrolled in another clinical trial
7. Have a history of documented invasive pneumococcal disease
8. Have received a corticosteroid therapy or immunoglobulin or blood products since birth
9. Will be unable to attend the schedule visits and to comply with the study procedures

Date of first enrolment
01/05/2005

Date of final enrolment
31/12/2006

Locations

Countries of recruitment
Philippines

Study participating centre
Research Institute for Tropical Medicine
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1781

Sponsor information

Organisation
Research Institute of Tropical Medicine (Philippines)

ROR
https://ror.org/01g79at26

Funder(s)

Funder type
Research organisation

Funder Name
World Health Organization (WHO)/Department of Immunisation, Vaccines and Biologicals (IVB) (Switzerland)

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	01/06/2009		Yes	No