

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

Submission date 04/08/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 22/09/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/07/2009	Condition category Infections and Infestations	<input type="checkbox"/> 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Prevention

Participant information sheet

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 measure

Not provided at time of registration

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/05/2005

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

Age group

Child

Sex

Both

Target number of participants

900

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 $\geq 38^{\circ}\text{C}$)
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
Muntinlupa City
Philippines
1781

Sponsor information

Organisation

Research Institute of Tropical Medicine (Philippines)

Sponsor details

Department of Health Compound
FILINVEST Corporate City
Alabang
Muntinlupa City
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1781

Sponsor type

Research organisation

Website

<http://www.ritm.gov.ph/>

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

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	01/06/2009		Yes	No