

Alternative vaccination schedules with pneumococcal polysaccharide/protein conjugate vaccine: immunogenicity of the prime-booster approach among Gambian infants

Submission date 04/08/2004	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 22/09/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 27/09/2007	Condition category Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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/RPC033

Study information

Scientific Title

Study objectives

Following previous encouraging findings from safety and immunogenicity studies using conjugate Pnc and Hib vaccines in the Gambia, we propose to evaluate the safety and immunogenicity of 7-valent Pnc conjugate (4, 6B, 9V 14 18C 19F 23F) manufactured by Wyeth Lederle Vaccine USA, using different vaccination schedules. The aim is to determine whether fewer doses started earlier in life with or without a booster dose of Pnc polysaccharide can induce a protective antibody response throughout infancy and early childhood. 675 young infants, residing in sites where the large efficacy (Pnc) trial is on-going, will be randomly allocated to one of 3 vaccination schedules using the 7-valent conjugate vaccine to assess the magnitude, duration and quality of the antibody- response to 1-2 doses with or without a booster dose in Upper River Division of The Gambia. The impact of this vaccination schedule on carriage of pneumococci will also be determined.

The data from this immunogenicity study and the larger on-going efficacy trial could provide important data for an informed policy decision in developing countries. We propose to use 7-valent vaccine since it is licensed and available, but would be guided by WHO as to the suitability and availability of other possible conjugate vaccines.

General objectives:

Evaluating the safety and antibody response to 1 or 2 doses of 7-valent conjugate pneumococcal (Pnc) vaccine given early in life with a booster dose of polysaccharide, compared with a standard 3-dose regimen.

Specific primary objectives:

1. To determine the immunogenicity of a 7-valent Pnc Conjugate vaccine at ages 18 weeks and 9 months, after one, two and three doses of conjugate vaccines
2. To evaluate the secondary immune response (antibody) to Pnc polysaccharide vaccine at age 10 months after one, two or three doses of 7-valent conjugate vaccine

Secondary objectives:

1. To evaluate persistence of antibody at age 15 months
2. To evaluate evidence of memory response following Conjugate vaccines using assays of antibody avidity and affinity
3. To determine naso-pharyngeal carriage of vaccine and non-vaccine serotypes at ages 6 weeks, 18 weeks, 10 and 15 months

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Gambia Government/Medical Research Council (MRC) Laboratories Joint Ethics Committee on the 5th October 2004.

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Pneumococcus/vaccines

Interventions

Group 1: Infants here will receive their only dose of a 7-valent pneumococcal conjugate vaccine at 6 weeks of life and a dose of polysaccharide vaccine at 9 months.

Group 2: A dose of conjugate vaccine will be offered at 6 and 14 weeks, and a dose of polysaccharide at 9 months.

The third group (3) will be recruited and vaccinated at 6, 10 and 14 weeks of life with the study conjugate vaccine and with the polysaccharide vaccine at 9 months.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Pneumococcal polysaccharide/protein conjugate vaccine

Primary outcome(s)

1. Immunogenicity of 7-valent pneumococcal conjugate vaccine at ages 18 weeks and 11 months after one, two and three doses of conjugate vaccines, measuring for antibody concentrations greater than or equal to 0.35 ug/ml
2. Secondary immune response (antibody) to pneumococcal polysaccharide vaccine at age 11 months after one, two or three doses of 7-valent conjugate vaccine (antibody concentrations greater than or equal to 0.35 ug/ml)

Key secondary outcome(s)

1. Persistence of antibody at age 15 months of age
2. Evidence of memory response following Conjugate vaccines using assays of antibody avidity and affinity
3. Naso-pharyngeal carriage of vaccine and non-vaccine serotypes at ages 18 weeks, 11 and 15 months of age
4. Monitoring for safety and local reaction up to 15 months of age. Two main aspects of the safety surveillance will be analysed:
 - 4.1. Serious Adverse Events (SAE)
 - 4.2. Local and Systemic reactions

Antibody concentrations to serotypes covered by the 7-valent conjugate vaccine (4, 6B, 9V, 14, 18C, 19F, and 23F) as well as antibody concentration to selected serotypes covered by the polysaccharide vaccine (1, 3, 5 and 12) will be measured.

Completion date

01/01/2007

Eligibility

Key inclusion criteria

Babies will be recruited when they present for first dose of Diphtheria, Pertussis, Tetanus (DPT)-Haemophilus influenzae type b (Hib) vaccine and written informed consent obtained at that time

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Not Specified

Sex

Not Specified

Key exclusion criteria

1. Babies born to known human immunodeficiency virus (HIV) positive mothers
2. Those with neurological abnormality
3. No parental consent
4. Established pneumococcal disease

Date of first enrolment

01/05/2005

Date of final enrolment

01/01/2007

Locations

Countries of recruitment

Gambia

Study participating centre

Medical Research Council Laboratories

Banjul

Gambia

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Sponsor information

Organisation

Medical Research Council Laboratories (The Gambia)

ROR

<https://ror.org/025wfj672>

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