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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 22/09/2004	**Overall study status** Completed	
Last Edited 27/09/2007	**Condition category** 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

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

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
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 measure
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 pnuemococcal 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)

Secondary outcome measures
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.

Overall study start date
01/05/2005

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

Age group
Not Specified

Sex
Not Specified

Target number of participants
675

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
-

Sponsor information

Organisation
Medical Research Council Laboratories (The Gambia)

Sponsor details
Fajara
Banjul
Gambia
-

Sponsor type
Research council

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

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