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Neonatal immunisation with pneumoccal conjugate vaccines: immunogenicity and the generation memory (Kenya)

Submission date	Recruitment status	[X] Prospectively registered
04/08/2004	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
22/09/2004	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
13/09/2007	Infections and Infestations	[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
WHO/RPC028

Study information

Scientific Title

Study objectives
Current hypothesis as of 13/09/2007:
In Kenyan children under 2 years of age, 23% of deaths from invasive pneumococcal disease occur in the first 14 weeks of life. Expanded Programme on Immunisation (EPI) vaccines are administered at 6, 10 and 14 weeks. Earlier vaccination against pneumococcus may prevent deaths of very young infants. This study examines whether 7-valent Pneumococcal Conjugate Vaccine (PCV) given on the first 72 hours of life is safe and whether it provides an adequate immunological response, including development of immunological memory, when compared to a regime in which the first dose is given at 6 weeks. 300 children will be randomised to one of two regimes; PCV at birth (up to 72 hours), 10 and 14 weeks or PCV at 6, 10 and 14 weeks. The safety and basic immunogenicity data will be analysed after a first phase of 60 children and a further phase of 240 children will be recruited if the results are found to be satisfactory.

Please note that the change to this hypothesis was made due to an initial protocol modification, where the 'birth' dose was amended from 24 hours to 72 hours. No other area of this trial was amended.

Previous hypothesis:
In Kenyan children under 2 years of age, 23% of deaths from invasive pneumococcal disease occur in the first 14 weeks of life. Expanded Programme on Immunisation (EPI) vaccines are administered at 6, 10 and 14 weeks. Earlier vaccination against pneumococcus may prevent deaths of very young infants. This study examines whether 7-valent Pneumococcal Conjugate Vaccine (PCV) given on the first day of life is safe and whether it provides an adequate immunological response, including development of immunological memory, when compared to a regime in which the first dose is given at 6 weeks. 300 children will be randomised to one of two regimes; PCV at birth, 10 and 14 weeks or PCV at 6, 10 and 14 weeks. The safety and basic immunogenicity data will be analysed after a first phase of 60 children and a further phase of 240 children will be recruited if the results are found to be satisfactory.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Kenya Medical Research Institute (KEMRI)/National Ethical Review Committee on the 27th October 2003
2. World Health Organization (WHO) Ethics Review Committee on the 18th September 2003 (renewed annually)

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design

Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Pneumococcus/vaccines

Interventions
Infants will receive 7-valent conjugate pneumococcal vaccine (PCV7) at birth (up to 72 hours - see point mentioned in hypothesis above), 6 and 10 weeks (group 1) or at 6, 10 and 14 weeks (group 2) along with routine Expanded Program of Immunisation (EPI) vaccines. Infants in each group will be randomised to receive either PCV7 or 23-valent pneumococcal polysaccharide vaccine at 9 months of age. Blood will be collected for measurement of antibody response prior to vaccine, 4 weeks after the primary series and pre- and 4 weeks post-booster dose. All infants will have Nasopharyngeal (NP) swabs collected at 18 weeks and 9 months of age that will be cultured for pneumococcus.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Pneumococcal Conjugate Vaccine (PCV)

Primary outcome measure
1. Clinical safety data in children vaccinated at birth compared to children vaccinated first at 6 weeks of life
2. Immunogenicity as measured by anti-capsular Immunoglobulin G (IgG) Enzyme-Linked Immuno-Sorbent Assay (ELISA) to serotypes in the vaccine, measured after a complete primary course at 18 weeks.

Secondary outcome measures
1. Immunogenicity as measured by anti-capsular IgG ELISA after one or two doses of vaccine, of which one was given at birth
2. Immunological memory measured as IgG response to a booster vaccine dose (either PCV or 1 /5th dose pneumococcal polysaccharide vaccine with a 50% probability of each) at 36 weeks
3. Functional immune response to first vaccination at birth as measured by prevalence of nasopharyngeal colonisation with S. pneumoniae at 18 and 36 weeks
4. Interference with immune response to diphtheria and tetanus attributable to vaccination with PCV at birth as measured by diphtheria and tetanus antibody concentration at 18 weeks
5. Interference with immune response to measles vaccine given at 36 weeks measured by anti-measles antibodies at 37 weeks
6. Effect of (maternal) pre-existing pneumococcal, diphtheria and tetanus antibody levels at

birth on immune response to the primary course of PCV, and Diphtheria Pertussis Tetanus (DPT) vaccine.

Overall study start date
01/11/2004

Completion date
31/10/2006

Eligibility

Key inclusion criteria
1. Healthy infants born to mothers tested human immunodeficiency virus (HIV) negative in the voluntary counselling and testing service
2. Not known to have congenital immune deficiency
3. Birth weight greater than 2500 g
4. Informed consent

Participant type(s)
Patient

Age group
Child

Sex
Both

Target number of participants
300

Key exclusion criteria
1. Infants requiring ongoing hospitalisation after birth
2. Suspected immune deficiency
3. Participation in another clinical trial

Any child who suffers a serious adverse event directly attributable to pneumococcal vaccination will be excluded from continued participation.

Date of first enrolment
01/11/2004

Date of final enrolment
31/10/2006

Locations

Countries of recruitment
Kenya

Switzerland

Study participating centre
World Health Organization
Geneva-27
Switzerland
CH-1211

Sponsor information

Organisation
Kenya Medical Research Institute (Kenya)

Sponsor details
PO Box 54840
Nairobi
Kenya
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Sponsor type
Research organisation

Website
http://www.kemri.org/

ROR
https://ror.org/04r1cxt79

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