ISRCTN46147225 https://doi.org/10.1186/ISRCTN46147225

Phase III, double-blind, randomised, placebo-controlled trial to evaluate efficacy against radiological pneumonia and invasive pneumococcal disease in Gambian infants

Submission date
10/11/2004

Recruitment status
No longer recruiting

Registration date
05/04/2005

Overall study status
Completed

Last Edited
09/11/2007

Condition category
Infections and Infestations

[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RPC096

Study information

Scientific Title

Acronym
PVT

Study objectives
To assess the efficacy of a nine-valent pneumococcal conjugate vaccine in children.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Phase III, double-blind, randomised, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

Participant information sheet

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

Interventions
Treatment group:
Nine-valent pneumococcal/polysaccharide protein conjugate vaccine which contains 2 µg of type 1, 4, 5, 9V, 14, 19F, 23F polysaccharides, 4 µg of type 6B polysaccharide and 2 µg of type 18 oligosaccharide linked to the diphtheria toxoid protein CRM197, reconstituted with DPT-Hib (Tetramune™) from the same manufacturer

Placebo group:
Lyophilised placebo cake reconstituted with Tetramune™

Intervention Type
Other

Phase
Phase III

Primary outcome measure
First episode of radiological pneumonia

Secondary outcome measures
1. Clinical or severe clinical pneumonia
2. Invasive pneumococcal disease
3. All-cause admissions

Overall study start date
01/08/2000

Completion date
01/01/2004

Eligibility

Key inclusion criteria
1. Infants aged at least 6 weeks and less than one year
2. Resident in study area
3. Written informed consent obtained from mother

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Weeks

Upper age limit
1 Years

Sex
Both

Target number of participants
Approx. 17500

Key exclusion criteria
1. Aged less than 6 weeks or more than 1 year
2. Not resident in study area
3. Planning to move out of study area within 4 months
4. Previous receipt of Diphtheria, Pertussis, Tetanus (DPT)-Haemophilus influenzae type b (Hib) vaccine
5. Uncertain prior vaccination record
6. Serious chronic illness

7. Inclusion in previous vaccine trial
8. Failure of family to give consent

Date of first enrolment
01/08/2000

Date of final enrolment
01/01/2004

Locations

Countries of recruitment
Gambia

Switzerland

Study participating centre
20, Avenue Appia
Geneva-27
Switzerland
CH 1211

Sponsor information

Organisation
National Institute of Allergy and Infectious Diseases - Division of Microbiology and Infectious Diseases (USA)

Sponsor details
6610 Rockledge Drive, Rm 6037
Bethesda
United States of America
20892
+1 3014022126
ehorigan@niaid.nih.gov

Sponsor type
Government

ROR
https://ror.org/043z4tv69

Funder(s)

Funder type
Research organisation

Funder Name
National Institutes of Health (NIH) (USA)

Alternative Name(s)
Institutos Nacionales de la Salud, US National Institutes of Health, NIH

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

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

Funder Name
Bill and Melinda Gates Foundation (USA)

Alternative Name(s)
Bill & Melinda Gates Foundation, Gates Foundation, BMGF, B&MGF, GF

Funding Body Type
Government organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United States of America

Funder Name
United States Agency for International Development (USAID) (USA)

Alternative Name(s)
U.S. Agency for International Development, Agency for International Development, USAID

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United States of America

Funder Name
Medical Research Council (UK)

Alternative Name(s)
Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/03/2005		Yes	No