

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

<b>Submission date</b> 10/11/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 05/04/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 09/11/2007	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

**Protocol serial number**  
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

**Study type(s)****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(s)**

First episode of radiological pneumonia

**Key secondary outcome(s)**

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

**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

## Healthy volunteers allowed

No

## Age group

Child

## Lower age limit

6 weeks

## Upper age limit

1 years

## Sex

All

## 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)

### ROR

<https://ror.org/043z4tv69>

## Funder(s)

### Funder type

Research organisation

### Funder Name

National Institutes of Health (NIH) (USA)

### Alternative Name(s)

US National Institutes of Health, Institutos Nacionales de la Salud, NIH, USNIH

### 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, Gates Learning Foundation, William H. 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, Medical Research Committee and Advisory Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	Results	01/03/2005		Yes	No