

# 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

**Contact name**  
Dr Felicity Cutts

**Contact details**  
20, Avenue Appia  
Geneva-27  
Switzerland  
CH 1211  
cuttsf@who.int

## 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?
<a href="#">Results article</a>	Results	01/03/2005		Yes	No