

# Community randomised controlled trial to assess the impact of vaccination with a pneumococcal conjugate vaccine on nasopharyngeal carriage of pneumococci in the Gambia

**Submission date**

02/06/2006

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

04/08/2006

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

04/10/2013

**Condition category**

Infections and Infestations

☐ Individual participant data

**Plain English summary of protocol**

Not provided at time of registration

## Contact information

**Type(s)**

Scientific

**Contact name**

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## Additional identifiers

EudraCT/CTIS number

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

SCC 1032

## **Study information**

**Scientific Title**

**Acronym**

Vilage study

**Study objectives**

It is likely that Prevenar®, a seven-valent pneumococcal conjugate vaccine, will soon be introduced into childhood immunisation programme in The Gambia. Pneumococci of serotypes 1 or 5 are important causes of invasive disease in The Gambia but are found infrequently in the nasopharynx and are not contained in Prevenar®. Could introduction of Prevenar® enhance their ability to establish themselves in the nasopharynx and subsequently to cause invasive disease?

In order to study the effects of maximum immune pressure of the kind that will be seen only several years after routine use of the vaccine, we propose to study the effects of vaccination of a whole community as well as that of vaccinating just the infant population.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

The Gambia Government/Medical Research Council (MRC) Laboratories Joint Ethics Committee, approved on 27/02/2006, reference number: SCC 1032

**Study design**

Community randomised controlled pneumococcal vaccination 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**

Pneumococcal infection or colonisation

**Interventions**

All young children who enter the trial will receive three doses of pneumococcal conjugate vaccine given at ages 2, 3 and 4 months through the Expanded Programme on Immunisation (EPI) programme. Infants under the age of three months and all children aged up to 11 months at the time that the study starts will receive three doses of vaccine at monthly intervals during the next three-month period. Children aged 12 - 30 months will receive two doses of pneumococcal conjugate vaccine given at an interval of a month. All subjects above the age of 30 months living in villages in group one will receive a single dose of pneumococcal conjugate vaccine; those living in group two villages will receive a single dose of control vaccine.

**Intervention Type**

Drug

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

Prevenar®

**Primary outcome measure**

1. Differences in the prevalence of nasopharyngeal carriage of pneumococci of vaccine or of non-vaccine serotype in study villages after vaccination
2. Differences in the prevalence of carriage with serotype 1 and serotype 5 pneumococci will be of particular importance

**Secondary outcome measures**

1. Acquisition rates of nasopharyngeal carriage in newborns resident in vaccinated or control villages
2. Evidence for an increased rate of capsular switching in villages where community-wide pneumococcal conjugate vaccination has been introduced
3. Measurements of Immunoglobulin G (IgG) and Immunoglobulin A (IgA) levels in serum and saliva

**Overall study start date**

01/07/2006

**Completion date**

01/07/2009

**Eligibility****Key inclusion criteria**

Resident of one of 21 Gambian villages

**Participant type(s)**

Patient

**Age group**

Child

**Sex**

Both

**Target number of participants**

7,500

**Key exclusion criteria**

1. Failure of the family/subject to give consent
2. Non-residence in the villages
3. Declared intent of the family/subject to leave the study area permanently within the following three months
4. Previous exposure to a conjugate pneumococcal vaccine

**Date of first enrolment**

01/07/2006

**Date of final enrolment**

01/07/2009

**Locations****Countries of recruitment**

Gambia

**Study participating centre**

MRC Laboratories

Banjul

Gambia

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**Sponsor information****Organisation**

Medical Research Council (UK)

**Sponsor details**

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London

United Kingdom

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**Sponsor type**

Research council

**Website**

<http://www.mrc.ac.uk>

**ROR**

<https://ror.org/03x94j517>

## Funder(s)

**Funder type**

Research council

**Funder Name**

Medical Research Council (UK) - core funding

**Funder Name**

Wyeth Pharmaceutical Inc. (USA)

## 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>	indirect effect results	01/09/2012		Yes	No
<a href="#">Results article</a>	nasopharyngeal carriage results	01/09/2012		Yes	No
<a href="#">Results article</a>	antibody concentration results	01/12/2012		Yes	No
<a href="#">Results article</a>	results	27/09/2013		Yes	No