

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

Protocol serial number

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

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

Completion date

01/07/2009

Eligibility

Key inclusion criteria

Resident of one of 21 Gambian villages

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Sex

All

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)

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

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	indirect effect results	01/09/2012		Yes	No
Results article	nasopharyngeal carriage results	01/09/2012		Yes	No
Results article	antibody concentration results	01/12/2012		Yes	No
Results article	results	27/09/2013		Yes	No