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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 [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/08/2006	**Overall study status** Completed	
Last Edited 04/10/2013	**Condition category** Infections and Infestations	

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
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
-

Sponsor information

Organisation
Medical Research Council (UK)

Sponsor details
20 Park Crescent
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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?
Results article	indirect effect results	01/09/2012		Yes	No
Results article	nasopharyngeal carrieage results	01/09/2012		Yes	No
Results article	antibody concentration results	01/12/2012		Yes	No
Results article	results	27/09/2013		Yes	No