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A study to assess the impact of the pneumococcal conjugate vaccination programme on carriage of pneumococci in children eligible for vaccination and their household contacts

Submission date
13/01/2012

Recruitment status
No longer recruiting

Registration date
02/02/2012

Overall study status
Completed

Last Edited
27/07/2015

Condition category
Infections and Infestations

[X] Prospectively registered

[_] Protocol

[_] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims

The pneumococcus germ lives in the space behind the nose and throat of up to 50% of children without causing any ill effects. It can spread from one person to another through touching, coughing and sneezing. Occasionally, however, pneumococcus can cause serious infections (especially in young children), including meningitis, pneumonia and septicaemia. Prevenar® (also known as PCV7) is a vaccine that protects against the 7 most common types (also known as serotypes) of the pneumococcus germ which cause serious infections in children. This was introduced in the UK childhood immunisation programme in September 2006 and was offered to all young children born after September 2004. This vaccine was very effective in preventing serious infections caused by the 7 pneumococcal serotypes the vaccine aims to protect, but did not have any impact on the other serotypes of pneumococcus that continued to cause serious infections. In April 2010, therefore, Prevenar® was replaced in the UK national childhood immunisation programme by a new vaccine that protects against 13 different pneumococcal serotypes (Prevenar13®, PCV13).

Pneumococcal conjugate vaccines such as Prevenar® and Prevenar13® protect against serious infections and also prevent the pneumococcus germ being carried in the nose of vaccinated children, which means that vaccinated children cannot pass the germs to other unvaccinated children or to adults or the elderly, therefore they will also be protected from serious pneumococcal infections. The researchers would like to check how effective the new Prevenar13® vaccine is at preventing the pneumococcus germ being carried in the nose of vaccinated children and their family members. In those children and adults who are found to carry the pneumococcus germ, the researchers are also interested in finding out which of the pneumococcal serotypes are being carried at present. It is hoped that the information we collect will help us predict the likely long-term impact of Prevenar13® in the UK.

This study aims to estimate overall and serotype-specific pneumococcal carriage rates in children immunised with the different pneumococcal conjugate vaccines and their household contacts.

The researchers also plan to compare changes in carriage serotypes by age group with previous carriage studies performed in 2001/02 and 2008/09 in children and adults in the same region.

Who can participate?
Households with at least one child aged between 1 and 4 years in Gloucestershire and Hertfordshire.

What does the study involve?
Participating GP surgeries will send, on behalf of the Health Protection Agency (HPA), an Information Pack about the study to potential participants using their own records and/or local child health computer systems. Those who indicate an interest in participating in the study will be contacted an HPA Vaccine Research Nurse, who will provide them with further information about the study and arrange to meet them at their home or their GP surgery at their convenience. At the meeting, the Vaccine Research Nurse will answer any questions the family may have, obtain written consent for all participants in the household if they meet the criteria to take part, complete a short questionnaire relating to the health and immunisation history of each participant and then obtain a single nasal swab, which may be uncomfortable but should only last a few seconds. Each participant will only have one nasal swab and participation in the study will end after providing the nasal swab. The swab will then be sent to an HPA laboratory to be tested for pneumococci.

What are the possible benefits and risks of participating?
There are no direct benefits for the participants in taking part in this study, but the researchers hope that the results of this study allow them to assess the likely long-term effectiveness of the current pneumococcal immunisation programme and may be used to inform future national vaccination policy.
Because this study will only involve taking one nasal nose swab from each participant, there are no disadvantages or risks in taking part apart from minor discomfort when the swab is taken. All vaccine research nurses are fully trained and experienced collecting nasal swabs.

Where is the study run from?
The study is being conducted by the Health Protection Agency (HPA), which is an independent body that protects the health and well-being of the population and plays a critical role in protecting people from infectious diseases. There are currently 23 GP practices in Gloucestershire and Hertfordshire who have agreed to help recruit participants for this study

When is the study starting and how long is it expected to run for?
The study is expected to begin in March 2012 and to take 12 months to complete.

Who is funding the study?
Department of Health (UK)

Who is the main contact?
Dr Shamez Ladhani
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RSRSG 11/13

Study information

Scientific Title
A cross-sectional community-based study to assess the impact of pneumococcal conjugate vaccination programme on the carriage of pneumococci in children eligible for vaccination and their household contacts

Acronym
Pneucast13

Study objectives
Replacement of the 7-valent pneumococcal conjugate vaccine (PCV7) with the 13-valent vaccine (PCV13) in the United Kingdom in April 2010 has resulted in a change in nasopharyngeal carriage of pneumococcal serotypes in young children and their household contacts.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London - Hampstead Research Ethics Committee, ref: 11/LO/1998

Study design
Cross-sectional community based study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Invasive Pneumococcal Disease

Interventions
Participating General Practitioners (GP) in Hertfordshire and Gloucestershire in the UK will identify potential participants and provide parents/legal guardians with an information pack about the study on behalf of the Health Protection Agency. Families expressing an interest in participating will be contacted by one of the Vaccine Research Nurses, who will arrange to meet the family, obtain written consent and take one nasal swab from each participant who fulfils the inclusion criteria. The samples will then be sent to HPA Colindale and cultures for Streptococcus pneumoniae.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
1. Pneumococcal carriage rates for PCV13 and non-PCV13 serotypes in children aged <5 years two years after the introduction of PCV13
2. Pneumococcal carriage rates for PCV13 and non PCV13 serotypes in older children and adolescents (aged 5-20 years) and adults (aged >20 years) two years after the introduction of PCV13
3. Invasiveness of any emerging replacement carriage serotypes by estimating case: carrier ratio (CCR) using national surveillance data for invasive pneumococcal disease

Secondary outcome measures
1. Carriage rates of individual serotypes
2. Compare carriage by PCV7/PCV13 vaccination status in vaccine eligible cohorts
3. Compare, by age-group, changes in carriage serotypes with previous carriage studies performed by the HPA in 2001/02 and 2008/09 in children and adults

Overall study start date
01/03/2012

Completion date

01/03/2013

Eligibility

Key inclusion criteria
1. At least one child aged 1 to 5 years in the household
2. Written informed consent obtained for the child's parent/legal guardian and participating household contacts

Participant type(s)
Other

Age group
Child

Lower age limit
1 Years

Upper age limit
5 Years

Sex
Both

Target number of participants
200 (+/-10%) children (index cases) aged 1-5 years and their household contacts

Key exclusion criteria
1. Moderate to severe cerebral palsy or other debilitating condition
2. Syndromes and neurological disorders affecting swallowing
3. Ear, nose & throat disorders affecting local anatomy for swabbing (e.g. malformed ears)
4. Confirmed or suspected immunodeficiency (congenital or acquired) or on immunosuppressive therapy

Date of first enrolment
01/03/2012

Date of final enrolment
01/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Health Protection Agency
London
United Kingdom
NW9 5EQ

Sponsor information

Organisation
Health Protection Agency (UK)

Sponsor details
c/o Dr John Stephenson
151 Buckingham Palace Road
London
United Kingdom
SW1W 9SZ

Sponsor type
Government

Website
http://www.hpa.org.uk/

ROR
https://ror.org/03sbpja79

Funder(s)

Funder type
Government

Funder Name
Department of Health (UK)

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	results	23/07/2014		Yes	No