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A phase III randomised, open label clinical trial evaluating the immunogenicity of a 10-valent pneumococcal conjugate vaccine booster compared to the standard 13-valent pneumococcal conjugate vaccine booster given at 12 months of age to healthy children who have received the 13-valent pneumococcal conjugate vaccine at 2 and 4 months of age

Submission date
29/06/2012

Registration date
29/06/2012

Last Edited
13/03/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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
2011-005102-30

IRAS number

ClinicalTrials.gov number
NCT01443416

Secondary identifying numbers
12221

Study information

Scientific Title
A phase III randomised, open label clinical trial evaluating the immunogenicity of a 10-valent pneumococcal conjugate vaccine booster compared to the standard 13-valent pneumococcal conjugate vaccine booster given at 12 months of age to healthy children who have received the 13-valent pneumococcal conjugate vaccine at 2 and 4 months of age

Study objectives
This is a study to evaluate an alternative booster for pneumococcal conjugate vaccination (PCV) for children at 12 months of age. Currently in the UK, a vaccine called Prevenar 13 (PCV-13), which contains 13 pneumococcal types attached to a molecule (carrier protein) called CRM197, is given to children at 2, 4 and 12 months of age. There is some evidence that a vaccine called Synflorix (PHiD-CV) may be at least as good as the currently used vaccine when given at 12 months of age. Although PHiDCV contains only 10 pneumococcal types, there is evidence that it generates crossreactive antibodies against two of the three additional types included in PCV-13 which might be enough to protect children against these disease types. Furthermore, previous studies have shown that PHiD-CV confers protection against a common otitis media pathogen in children called nontypeable H. influenzae (NTHi) by attachment to a carrier protein called Protein D, which is derived from NTHi. In addition, the use of a carrier protein, which is not closely related to an antigen included in any coadministered or previously administered routine vaccine minimises the risk of interference related to it.

More details can be found at http://public.ukcrn.org.uk/Search/StudyDetail.aspx?StudyID=12221

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/SC/0473; First MREC approval date 22/12/2011

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
GP practice

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Streptococcus pneumoniae vaccination

Interventions
Blood sampling: Study nurse/doctor at the participants' home.

Diary cards: Participants will be asked to record any local/general reactions to vaccine for 4 days after vaccination. In addition any medically significant adverse events occuring between the study visits are to be recorded. All concomitant medication used during this period will also be recorded.

Health assessment: Study nurse/doctor at the participants' home.

Routine vaccines: MMR-Hib-MenC

Study vaccine and comparator, Study nurse/doctor at the participants' home

Taking oral temperature, Prior to receive the vaccine, oral temperature will be recorded at the CCVTM clinic rooms

Study Entry : Single Randomisation only

Intervention Type
Biological/Vaccine

Phase
Phase III

Primary outcome measure
Not provided at time of registration

Secondary outcome measures
Not provided at time of registration

Overall study start date
05/04/2012

Completion date
31/10/2012

Eligibility

Key inclusion criteria
1. Aged 12 months (2 weeks to +6 weeks) at time of enrolment
2. Have received two doses of PCV13 at less than 6 months of age with a gap of at least 6 weeks between the two vaccinations
3. Have received all primary vaccines according to the UK routine immunisation schedule
4. Available for entire study period and whose parent/legal guardian can be reached by telephone
5. Healthy children as determined by medical history and physical examination, done by a study nurse (and/or study doctor if required, depending on the medical history of the participant and physical assessment), and judgment of the investigator
6. Parent/legal guardian must be able to complete all relevant study procedures during study participation

Participant type(s)
Patient

Age group
Child

Lower age limit
12 Months

Upper age limit
12 Months

Sex
Both

Target number of participants
Planned Sample Size: 168; UK Sample Size: 168

Key exclusion criteria
1. Previous receipt of pneumococcal vaccine other than the 13 valent pneumococcal conjugate vaccine (Prevenar 13®, Pfizer)
2. Receipt of the routine 12month immunisations (PCV13 (3rd dose), combined Haemophilus influenzae type b and serogroup C meningococcal glycoconjugate vaccine (HibMenC) or measles, mumps and rubella vaccine (MMR)
3. A previous anaphylactic reaction to any vaccine or vaccinerelated component
4. Contraindication to vaccination with pneumococcal conjugate vaccine
5. Bleeding diathesis or condition associated with prolonged bleeding time that would contraindicate intramuscular injection
6. Known or suspected immune deficiency or suppression
7. History of cultureproven invasive disease caused by S. pneumoniae
8. Major known congenital malformation or serious chronic disorder
9. Significant neurologic disorder or history of seizures including febrile seizure, or significant stable or evolving disorders such as cerebral palsy, encephalopathy, hydrocephalus, or other significant disorder
10. Receipt of blood products or gammaglobulin (including hepatitis B immunoglobulin and

monoclonal antibodies; e.g., Synagis B)
11. Parents who plan to move out of the geographical area where the study would be conducted

Date of first enrolment
05/04/2012

Date of final enrolment
31/10/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Paediatrics, Headley Way , Headington
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OX3 9DU

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Research Services
Clinical Trials and Research Governance
Headley Way
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Sponsor type
University/education

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
GlaxoSmithKline

Alternative Name(s)
GlaxoSmithKline plc., GSK plc., GSK

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

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?
Results article	results	01/07/2016		Yes	No
HRA research summary			28/06/2023	No	No