ISRCTN72858898 https://doi.org/10.1186/ISRCTN72858898

Persistence of antibodies six years after priming immunisation with Meningococcal C conjugate vaccine and response to the Hib-MenC (Menitorix®) vaccine in healthy children

Submission date 06/07/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 04/09/2006	**Overall study status** Completed	
Last Edited 28/07/2010	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Study website
http://www.paediatrics.ox.ac.uk/ovg/

Contact information

Type(s)
Scientific

Contact name
Dr Andrew Pollard

Contact details
Centre for Vaccinology and Tropical Medicine
Churchill Hospital
Oxford
United Kingdom
OX3 7LJ

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
OVG 2006/2

Study information

Scientific Title
A phase IV, single centre, open-label study to investigate the persistence of antibodies six years after priming immunisation with Meningococcal C conjugate vaccine and induction of long term immunological memory by assessing persistence of memory B cells and response to the Hib-MenC (Menitorix®) vaccine, in healthy children six to 12 years of age

Study objectives
To asess the persistence of antibodies, six years after priming immunisation with Meningococcal C conjugate vaccine and response to the Hib-MenC (Menitorix®) vaccine.

Please note that the following amendments have been made to this trial record as of 16/03/2009:
1. The public title has been changed from "A phase IV, single centre, open-label study to investigate the persistence of antibodies six years after priming immunisation with Meningococcal C conjugate vaccine and induction of long term immunological memory by assessing persistence of memory B cells and response to the Hib-MenC (Menitorix®) vaccine, in healthy children six to 12 years of age" to "Persistence of antibodies six years after priming immunisation with Meningococcal C conjugate vaccine and response to the Hib-MenC (Menitorix®) vaccine in healthy children". The original public title has been moved to the scientific title field.
2. The sponsor name has been amended from John Radcliffe Hospital (UK) to University of Oxford (UK) (due to incorrect sponsor name provided at time of registration).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Favourable opinion granted from Oxfordshire LREC B on 13 July 2006.

Study design
Phase IV single-centre open-label trial

Primary study design
Interventional

Secondary study design
Single-centre

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Meningococcal C and Haemophilus influenzae type B diseases

Interventions
All 250 participants will receive one dose of the Hib-MenC (Menitorix®) conjugate vaccine. Blood samples will be taken at zero, one and 12 months after the vaccine. In 75 participants only, blood will also be taken on day seven.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Menitorix®; (Haemophilus influenzae B [Hib] and Meningococcal C[MenC]) vaccine

Primary outcome measure
Serum bactericidal antibody to meningococcal serogroup C six years after priming immunisation.

Secondary outcome measures
1. Measurement of antibody and B cell responses and assessment of memory induction following the Hib-MenC (Menitorix®) vaccine
2. Number and nature of any adverse events occuring during the study

Overall study start date
14/08/2006

Completion date
16/06/2008

Eligibility

Key inclusion criteria
1. Participants parent or legally authorised representative is willing and able to give written informed consent for participation after the nature of the study has been explained
2. Male or Female, aged six years (+ zero days) to 12 years (+ 364 days) on the day of enrolment
3. In good health as determined by:
3.1. medical history
3.2. pre-vaccination check performed by a physician if indicated by history
3.3. clinical judgment of the investigator
4. Able (in the investigators opinion) and willing to comply with all study requirements including being available for all the visits scheduled in the study
5. Parent or legally authorised representative is willing to allow his or her childs (the participant s) General Practitioner to be notified of participation in the study and contacted if required for confirmation of vaccination history
6. Whose parent or legally authorised representative believes to their best knowledge that their child has received all the recommended vaccinations as part of the UK routine childhood immunisation schedule (including Haemophilus influenzae B (Hib) if aged six months to four years in April 2003 (received 4/2003 - 12/2004) and Meningococcal C (MenC) if aged six months

to 18 years in Nov 1999 (received 11/1999 - 06/2001) as part of the UK catch up vaccination campaigns)

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Have a history of any anaphylactic shock, asthma, urticaria or other allergic reaction after previous vaccinations or known hypersensitivity to any vaccine component
2. Axillary temperature more than or equal to 38.0°C or presence of any systemic illness on the day of enrolment
3. Have experienced significant acute or chronic infection within the previous seven days or have experienced fever (more than or equal to 38.0°C) within the previous three days
4. Receipt of systemic antibiotics (either oral or parenteral) will delay enrolment until at least 14 days after cessation of antibiotics, with the exception of beta-lactam antibiotics (examples: penicillin, amoxicillin, ceftriaxone, cefuroxime, cephalexin, etc.) who may be enrolled seven days after the last dose
5. Have a previous clinical or bacteriological or suspected diagnosis of meningitis
6. Have a history of household contact or intimate exposure to an individual with culture proven Neisseria meningitis or Hib disease in the previous 60 days
7. Have a present or suspected serious disease such as metabolic, cardiac, autoimmune, endocrine (including insulin dependent diabetes), significant hepatic or renal impairment or progressive neurological impairment
8. Have any immunodeficiency, including use of systemic corticosteroids for more than five days or in a daily dose more than 1 mg/kg/day prednisone or equivalent for less than or equal to five days in the previous 30 days (inhaled high-potency corticosteroids equivalent to budesonide 800 mcg/day or fluticasone 750 mcg/day)
9. Have a genetic anomaly e.g. Downs syndrome
10. Born after a gestation period of less than 36 weeks or more than 42 weeks
11. Have scheduled elective surgery or other procedures requiring general anaesthesia during the study
12. Have received of any blood, blood products or parenteral immunoglobulin preparation within the past 12 weeks
13. Have received any additional doses of Hib or MenC vaccines in addition to those given in accordance with the UK routine immunisation schedule or catch up campaigns
14. Participants who have participated in another research study involving an investigational

product in the past 12 weeks or are planning to receive a vaccine or investigational product within the next month
15. Have a known bleeding diathesis or any condition associated with a prolonged bleeding time
16. Any other significant disease or disorder which, in the opinion of the investigator, may either put the participant at risk because of participation in the study, or may influence the result of the study, or the participants ability to participate in the study

Date of first enrolment
14/08/2006

Date of final enrolment
16/06/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Centre for Vaccinology and Tropical Medicine
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
c/o Ms Heather House
Clinical Trials Office
Manor House
John Radcliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 9DZ

Sponsor type
Hospital/treatment centre

Website

http://www.admin.ox.ac.uk/rso/contactus/ctrg.shtml

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
GSK Biologicals (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	15/06/2010		Yes	No