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A single centre randomised clinical trial to assess the antibody response to a 23-valent pneumococcal polysaccharide vaccine administered to adults aged between 50 - 70 years following a 0, 1 or 2 dose priming immunisation with a 7-valent pneumococcal conjugate vaccine

Submission date
04/07/2006

Registration date
28/07/2006

Last Edited
24/07/2013

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

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

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
Oxford Vaccine Group
Department of Paediatrics
University of Oxford
Centre for Clinical Vaccinology and Tropical Medicine
Churchill Hospital
Old Road
Headington

Oxford
United Kingdom
OX3 7LJ
+44 (0)1865 857420
ovg@paediatrics.ox.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
6097A1-800

Study information

Scientific Title

Acronym
Protecting adults against pneumococcal disease

Study objectives
To assess the antibody response (absolute antibody concentration) to a 23-valent pneumococcal polysaccharide vaccine (Pn23) after a 0, 1 or 2 dose priming immunisation with heptavalent pneumococcal conjugate vaccine (Pnc7).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Oxfordshire A Local Research Ethics Committee (LREC) on the 14th September 2006 (ref: 06/Q1604/121).

Study design
Randomised clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
Pneumococcal disease

Interventions
Interventions used are the Heptavalent pneumococcal conjugate vaccine (Prevenar ®, Wyeth Vaccines) and 23-valent pneumococcal polysaccharide vaccine (Pneumovax® II, Sanofi Pasteur MSD). Participants will be randomised to receive either:
1. Two doses of the 7-serotype vaccine (Prevenar®) followed by one dose of the 23-serotype vaccine (Pneumovax® II)
2. One dose of the 23-serotype vaccine (Pneumovax® II) followed by two doses of the 7-serotype vaccine (Prevenar®)
3. One dose of the 7-serotype vaccine (Prevenar®) followed by one dose of the 23-serotype vaccine (Pneumovax® II, followed by a further dose of the 7-serotype vaccine (Prevenar®)

All vaccines will be administered at 0, 6 and 12 months.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Heptavalent pneumococcal conjugate vaccine (Prevenar ®), 23-valent pneumococcal polysaccharide vaccine (Pneumovax® II)

Primary outcome measure
Absolute antibody concentration to Pn23 after a one or 2 dose priming immunisation with Pnc7.

Secondary outcome measures
1. Characterisation and measurement of the B cell responses and assessment of memory induction following the three different immunisation regimes
2. Number and nature of any adverse events occurring during the study

Overall study start date
01/09/2006

Completion date
31/08/2008

Eligibility

Key inclusion criteria

1. Healthy adults aged 50 - 70 years inclusive
2. In good health as determined by:
2.1. Medical history
2.2. History-directed physical examination
2.3. Clinical judgment of the investigator
3. Able (in the Investigators opinion) and willing to comply with all study requirements including be available for all the visits scheduled in the study
4. Willing to allow his or her General Practitioner and consultant, if appropriate, to be notified of participation in the study

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
348

Key exclusion criteria
1. Have previously received any pneumococcal vaccine
2. Have received vaccination with a vaccine containing either CRM197 or Diphtheria toxoid within the past 12 months
3. Have a previous ascertained or suspected disease caused C. diphtheriae, or Pneumococcus
4. Have a history of any anaphylactic shock, asthma, urticaria or other allergic reaction after previous vaccinations or known hypersensitivity to any vaccine component
5. Have a known or suspected autoimmune disease or impairment /alteration of immune function resulting from (for example):
5.1. Receipt of any immunosuppressive therapy
5.2. Receipt of immunostimulants
5.3. Congenital or acquired immunodeficiency, or receipt of immunosuppressive therapy such as anti-cancer chemotherapy or radiation therapy within the preceding 6 months or long-term systemic corticosteroid therapy* (*prednisolone or equivalent for more than two consecutive weeks within the past 3 months)
6. Have a suspected or known human immunodeficiency virus (HIV) infection or HIV related disease
7. Have received blood, blood products and/or plasma derivatives or any parenteral immunoglobulin preparation in the past 3 months
8. Have a known bleeding diathesis, or any condition that may be associated with a prolonged bleeding time
9. Have any condition which, in the opinion of the investigator, might interfere with the evaluation of the study objectives
10. Participation in another clinical trial investigating a vaccine, a drug, a medical device, or a medical procedure

Date of first enrolment
01/09/2006

Date of final enrolment
31/08/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Oxford Vaccine Group
Oxford
United Kingdom
OX3 7LJ

Sponsor information

Organisation
University of Oxford (UK)

Sponsor details
Clinical Trials Office
Manor House
John Radcliffe Hospital
Headington
Oxford
England
United Kingdom
OX3 7LJ
+44 (0)1865 743004
heather.house@admin.ox.ac.uk

Sponsor type
University/education

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

ROR
https://ror.org/052gg0110

Funder(s)

Funder type
Industry

Funder Name
Wyeth Vaccines (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	result	15/03/2011		Yes	No
Results article	results	01/05/2012		Yes	No
Results article	results	01/03/2013		Yes	No