

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	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 28/07/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 24/07/2013	Condition category Infections and Infestations	<input type="checkbox"/> 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

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Contact details

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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

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+44 (0)1865 743004

heather.house@admin.ox.ac.uk

Sponsor type

University/education

Website

<http://www.admin.ox.ac.uk/rso/contactus/ctrng.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