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Evaluation of pneumococcal conjugate vaccine (Prevenar) in patients with myeloma and chronic lymphocytic leukaemia

Submission date 23/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 14/03/2006	**Overall study status** Completed	
Last Edited 18/10/2017	**Condition category** Cancer	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
9818P

Study information

Scientific Title
Evaluation of pneumococcal conjugate vaccine (Prevenar) in patients with myeloma and chronic lymphocytic leukaemia

Study objectives
Null hypotheses:
1. The pneumococcal conjugate vaccine (Prevenar) will not provide adequate immunity from pneumococcal disease as measured by antibody levels
2. The pneumococcal conjugate vaccine (Prevenar) does not prime the immune system, resulting in improved responses to subsequent vaccination with the 23-valent polysaccharide vaccine

Ethics approval required
Old ethics approval format

Ethics approval(s)
The proposal was reviewed following submission to Central Office for Research Ethics Committees (COREC) by Salford and Trafford Local Research Ethics Committee on the 8th November 2005. The Research Ethics Committee reference number: 05/Q1404/229. The Committee was content to give a favourable opinion subject to clarification of points raised at the interview. Final approval has now been received dated 28/11/05.

Primary study design
Interventional

Study design
Interventional non-randomised open label trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Multiple myeloma and chronic lymphocytic leukaemia

Interventions
All study participants will be required to undertake three or four scheduled visits. If the patient is being seen regularly for follow up in the clinic, the trial visits will be scheduled to coincide with these to minimise the number of additional attendances.

Visit 1: the potential participants will be informed in detail about the study and given the opportunity to ask any further questions. If they wish to participate they will be formally screened against the exclusion criteria. Provided no contraindications are identified, they will be asked to sign a consent form. Predictable risks and inconveniences will be discussed. A full medical history will be taken, concurrent medication documented and physical examination performed. Details of disease stage will be obtained from the medical records. A case report form has been designed specifically to document all information required and to ensure standardisation. A small blood sample (6 ml) will then be taken for pre-immunisation antibody levels and evaluation of other markers of immune status. Vaccination with the conjugate vaccine will then be administered.

Visit 2: this will take place 8-10 weeks following visit 1. The case report form will be completed in a similar manner. A 2 ml blood sample is required for post-vaccination antibody levels. Following this, the second vaccination with the conjugate vaccine will be administered.

Visit 3: this will take place 8-10 weeks after the second visit. The case report form will be completed. If the patient has received the 23-valent polysaccharide vaccination in the previous

five years, the study will terminate at this point and a blood sample will be taken for antibody response and other markers of immune status (6 ml will be required). Subjects who have not received the 23-valent polysaccharide vaccine in the last five years will be vaccinated with this vaccine on this visit. From the group of patients receiving the vaccine only 2 ml of blood is required for post vaccination antibody levels.

Visit 4: only individuals vaccinated at visit 3 will be requested to attend. The visit will take place 6-8 weeks after the third visit. Blood samples will be taken for post immunisation antibody levels and other markers of immune status (6 ml blood).

Participants will also be asked if they would be available to attend for one extra visit for an additional blood test only, one week after the second vaccination. This test is optional and supplementary and aims to evaluate how the vaccine is stimulating another aspect of the immune response (cell mediated immunity), which may also be important in providing protection from disease. 15 ml of blood will be needed for this supplementary test.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Prevenar

Primary outcome(s)
To determine whether the pneumococcal conjugate vaccine (Prevenar) can provide immunity from invasive pneumococcal disease in a group of haematology patients at high risk of infective complications

Key secondary outcome(s)
1. To determine whether the immune response to the conjugate vaccine (Prevenar) differs between individuals naive to the 23-valent pneumococcal vaccine and those who have received at least one previous dose
2. To assess whether the response to subsequent vaccination with the 23-valent polysaccharide vaccine is enhanced by prior vaccination with the conjugate vaccine (Prevenar)
3. To determine the optimum dosage and schedule of the conjugate vaccine
4. To evaluate the immune response in relation to disease related variables. These will include disease stage, treatment and laboratory markers of the immune system function as a whole. This will improve our understanding of the mechanisms resulting in vaccine success and failure.

Completion date
30/04/2008

Eligibility

Key inclusion criteria
Patients with multiple myeloma as defined by the demonstration of:
1. Over 10% plasma cells in the bone marrow and at least one of the following:
a. Lytic lesions on radiographic X-ray imaging
b. A paraprotein in serum or urine

2. Patients with Chronic Lymphocytic Leukemia (CLL) as defined by the demonstration of a clonal population of B-lymphocytes with characteristic immunophenotype (CD5+, CD23+, weak expression of surface Ig (weak SIg), FMC7-negative) in peripheral blood, bone marrow or lymph node biopsy
3. Aged ≥18 years
4. Ability to give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Immunoglobulin therapy in the previous four months
2. General contraindications to immunisation as defined in the UK handbook - Immunisation against Infectious Disease
3. Currently receiving treatment prior to planned peripheral blood stem cell or bone marrow transplant
4. Less than six months post peripheral blood stem cell or bone marrow transplant
5. Receiving treatment with high dose steroids (monthly pulsed dexamethasone or >1 mg/kg of prednisolone as a continuous dose)
6. Platelets <30 x 10^9 /l
7. Prior vaccination with Prevenar
8. Prior vaccination with 23-valent pneumococcal vaccine in previous six months
9. Pregnancy
10. Previous splenectomy
11. Other secondary immunodeficiency state e.g. Human Immunodeficiency Virus (HIV) infection

Date of first enrolment
01/12/2005

Date of final enrolment
30/04/2008

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Clinical Haematology
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Sponsor information

Organisation
Central Manchester and Manchester Children's Hospital (UK)

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Charity

Funder Name
Charitable Funds from the Molecular Haematology Fund (9175)

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Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration