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Investigating the clinical use of 13-valent pneumococcal conjugate vaccine (Prevenar) in childhood acute lymphoblastic leukaemia

Submission date
21/10/2010

Recruitment status
No longer recruiting

Registration date
21/10/2010

Overall study status
Completed

Last Edited
20/05/2021

Condition category
Infections and Infestations

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

Plain English summary of protocol
https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-trial-looking-vaccine-prevent-infections-children-acute-lymphblastic-leukaemia

Study website
http://www.ctu.soton.ac.uk

Contact information

Type(s)
Scientific

Contact name
Dr Juliet Gray

Contact details
Southampton University Hospitals NHS Trust
Tremona Road
Southampton
United Kingdom
SO16 6YD
-
jcgray@soton.ac.uk

Additional identifiers

EudraCT/CTIS number
2009-011587-11

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
8541

Study information

Scientific Title
Investigating the clinical use of 13-valent pneumococcal conjugate vaccine (Prevenar) in childhood acute lymphoblastic leukaemia: a multicentre non-randomised interventional treatment trial

Acronym
PCV (Pneumococcal Conjugate Vaccine)

Study objectives
The main aim of this study is to produce evidence on which to base a vaccination guideline that will reduce the incidence of pneumococcal infection in children with acute leukoblastic leukaemia (ALL). This will be achieved by examining the efficacy of 13 valent conjugate pneumococcal vaccination (13vPCV) immunisation in this population. Our hypothesis is that 13vPCV will be sufficiently immunogenic to generate protective anti-pneumococcal immunity in children with ALL whilst they are receiving maintenance therapy and are most at risk of infection. However, it is possible that vaccination of children during treatment will not be effective due to the immunosuppressive effects of chemotherapy. Therefore vaccination with 13vPCV will also be tested in children at the end of their treatment and 6 months after completion of treatment. The earliest of these time points at which 13vPCV is found to achieve protective immunity will be adopted as the final recommendation for all children with ALL, in order to provide protection for as long as possible during and after their leukaemia therapy.

The main study question is therefore to identify the earliest time point that children with ALL can be effectively vaccinated with 13vPCV. In order to answer this, the study primary objective is to establish if 13vPCV can achieve protective levels of anti-pneumococcal antibodies:
1. During maintenance therapy
2. At the end of chemotherapy treatment
3. Six months after completion of treatment

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton and South West Hampshire REC, Committee B, 11/02/2010, ref: 09/HO504/112

Study design
Multicentre non-randomised interventional treatment trial

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

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
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
PCV-13 vaccine, single 0.5 ml dose of vaccine to each study participant.

Follow up length: 12 months
Study entry: other
Details: non-random allocation to treatment group, depending on current timepoint in ALL treatment

Intervention Type
Biological/Vaccine

Phase
Phase IV

Primary outcome measure
Serum concentrations of IgG anti-capsular polysaccharide antibodies to pneumococcal serotypes, measured at 0, 1 and 12 months post-immunisation

Secondary outcome measures
1. Nasopharyngeal carriage of pneumococcal sp (including serotpye and MLST), measured at 0 and 12 months post-immunisation
2. Opsonophagocytosis assay (OPA) against two pneumococcal serotypes, measured at 0, 1 and 12 months post-immunisation
3. Peripheral blood lymphocyte subsets, measured at 0 and 12 months post-immunisation
4. Serum concentrations of total immunoglobulins and IgG subclasses, measured at 0 and 1 months post-immunisation

Overall study start date
07/09/2010

Completion date
01/09/2012

Eligibility

Key inclusion criteria

1. Aged 2 to 18 years (inclusive), either sex
2. ALL confirmed by immunophenotyping at diagnosis
3. Currently receiving maintenance therapy as per UKALL 2003 treatment protocol, or treatment as per UKALL 2003 protocol completed within last 6 months
4. Informed consent of parent/guardian (+/- patient)

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 120; UK sample size: 120

Total final enrolment
118

Key exclusion criteria
1. Concomitant acquired or congenital immunodeficiency
2. Concomitant immunosuppressive medication within previous 3 months, other than maintenance chemotherapy as per UKALL 2003 protocol
3. Previous severe or anaphylactic reaction to PCV
4. Previous severe or anaphylactic reaction to diphtheria toxoid
5. Children with a contraindication to receipt of any vaccine or a specific vaccine as stated in the Department of Health Green Book on immunisation (DOH, 2006)
6. Pregnancy or lactation

Routine immunisation with PCV7 prior to ALL therapy is not an exclusion criteria

Date of first enrolment
07/09/2010

Date of final enrolment
01/09/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Southampton University Hospitals NHS Trust
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Southampton University Hospitals NHS Trust (UK)

Sponsor details
Tremona Road
Southampton
England
United Kingdom
SO16 6YD

Sponsor type
Hospital/treatment centre

Website
http://www.suht.nhs.uk/home.aspx

ROR
https://ror.org/0485axj58

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit (RfPB) Programme (ref: PB-PG-1207-15250)

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?
Basic results			20/05/2019	No	No
Results article	results	22/08/2020	18/06/2020	Yes	No
Results article	results	01/07/2020	18/06/2020	Yes	No
Plain English results			20/05/2021	No	Yes