Immunogenicity of pneumococcal vaccine in liver transplant recipients

Submission date	Recruitment status No longer recruiting	Prospectively registered	
21/05/2008		☐ Protocol	
Registration date 21/05/2008	Overall study status Completed Condition category	Statistical analysis plan	
		[X] Results	
Last Edited		Individual participant data	
24/02/2009	Infections and Infestations		

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Deepali Kumar

Contact details

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Additional identifiers

ClinicalTrials.gov (NCT)

NCT00152802

Protocol serial number

MCT-79196

Study information

Scientific Title

Immunogenicity of pneumococcal vaccine in liver transplant recipients: a randomised, double-blind, placebo-controlled, safety/efficacy study, single centre trial

Study objectives

It is hypothesised that the conjugate vaccine priming will provide an enhanced response in these immunosuppressed individuals who may respond poorly to standard vaccination.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Research Ethics Board of the University Health Network (Toronto) approved on the 10th September 2004 (ref: 04-0450-123TGH)

Study design

Randomised, double-blind (study participant and investigator), placebo-controlled, safety /efficacy study, single centre trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Pneumococcal vaccination

Interventions

- 1. The conjugate vaccine used will be Prevnar™ (Wyeth vaccines) 0.5 mL, once, intramuscularly
- 2. The polysaccharide vaccine Pneumovax® (Merck-Frosst) 0.5 mL, once, intramuscularly (I.M.)

Duration of follow-up = 2 years for all treatment arms

Contact for public queries:

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Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Primary outcome(s)

Antibody titres to the seven serotypes contained in conjugate vaccine (4, 6B, 9V, 14, 19F, 23F), 16 weeks.

Key secondary outcome(s))

- 1. Functional antibody concentration: the titre of functional antibody against the seven pneumococcal serotypes contained in the conjugate vaccine will be determined. Opsonophagocytic assay will be measured at time 0 and 16 weeks.
- 2. Adverse reactions: any adverse effects attributed to conjugate or polysaccharide vaccines will be documented. These will include local reactions such as redness, swelling, tenderness and systemic reactions such as fever.
- 3. Invasive pneumococcal disease: any occurrence of documented pneumococcal disease in vaccinated patients will be recorded

Completion date

28/02/2008

Eligibility

Key inclusion criteria

Male or female outpatients who fulfill the following criteria will be eligible for the study:

- 1. Liver transplant recipients greater than three months post-transplant
- 2. No prior pneumococcal vaccination within the last five years
- 3. Stable allograft function as evidenced by a alanine aminotransferase less than 10 times the upper limit of normal (umol/L) that is not worsening
- 4. Able to provide written informed consent and comply with study protocol
- 5. Aged greater than 16 years

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

- 1. Unable to provide informed consent or comply with protocol
- 2. Prior pneumococcal vaccination within five years of enrolment
- 3. Splenectomy
- 4. Admitted to hospital for acute illness
- 5. Febrile illness in the past two weeks

- 6. Intravenous immunoglobulin in the last six months
- 7. Current episode of allograft rejection
- 8. Currently on full-dose anticoagulation as a contraindication to intramuscular injection

Date of first enrolment

01/01/2005

Date of final enrolment

28/02/2008

Locations

Countries of recruitment

Canada

Study participating centre University of Alberta Hospital

Edmonton, Alberta Canada T6G 2B7

Sponsor information

Organisation

University Health Network (Canada)

ROR

https://ror.org/042xt5161

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-79196)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2008		Yes	No