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Immunogenicity of pneumococcal vaccine in liver transplant recipients

Submission date	Recruitment status	[_] Prospectively registered
21/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/05/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00152802

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet

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)
Prevnar™, Pneumovax®

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

Secondary outcome measures
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

Overall study start date
01/01/2005

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

Age group
Adult

Sex
Both

Target number of participants
130

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)

Sponsor details
Toronto General Hospital
585 University Ave
Toronto, Ontario
Canada
M5G 2N2

Sponsor type
Hospital/treatment centre

Website
http://www.uhn.ca/index.htm

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

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	results	01/10/2008		Yes	No