

# Immunogenicity of pneumococcal vaccine in liver transplant recipients

**Submission date**

21/05/2008

**Recruitment status**

No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**

21/05/2008

**Overall study status**

Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**

24/02/2009

**Condition category**

Infections and Infestations

☐ Individual participant data

**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

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:

Mr J Blackmore

Research Coordinator

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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

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**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?
<a href="#">Results article</a>	results	01/10/2008		Yes	No