Randomised trial to compare the clinical value of cyclosporin C12 and C2 monitoring after lung transplantation

Submission date	Recruitment status No longer recruiting	Prospectively registered			
16/05/2005		☐ Protocol			
Registration date	Overall study status	Statistical analysis plan			
08/07/2005	Completed	[X] Results			
Last Edited	Condition category	[] Individual participant data			
05/07/2018	Surgery				

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

Protocol serial number P00784

Study information

Scientific Title

Randomised trial to compare the clinical value of cyclosporin C12 and C2 monitoring after lung transplantation

Study objectives

Does improved control of the variability in exposure to cyclosporin by monitoring C2 in lung transplant recipients help to reduce the propensity of these patients to cyclosporin-associated side effects whilst maintaining effective immunosupression?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lung transplant recipients

Interventions

Patients will be randomised into 3 groups to compare the clinical value of both 'high' and 'low' C2 monitoring strategies with conventional C12 monitoring as a guide to cyclosporin Neoral dosage adjustment after lung transplantation.

Intervention Type

Procedure/Surgery

Phase

Not Specified

Primary outcome(s)

Renal function at 3 months post transplant

Key secondary outcome(s))

Not provided at time of registration

Completion date

01/04/2006

Eligibility

Key inclusion criteria

90 patients lung transplant:

- 1. Adult single or double lung and heart + lung transplant recipients (18 years and older)
- 2. Patients receiving Neoral as primary immunosuppression

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

- 1. Patients not giving voluntary, written informed consent to participate
- 2. Re-transplantation
- 3. Simultaneous kidney, pancreas, liver or bowel transplantation
- 3. Urine output <50 ml/hour and/or serum creatinine ≥170 mmol/l at the most recent investigation prior to transplantation
- 4. Renal replacement therapy or any form of renal support such as continuous veno-venous haemofiltration (CVVH) or dialysis before transplantation or within the first post-operative week
- 5. Patients receiving tacrolimus or sirolimus as primary immuno-suppression in place of Neoral

Date of first enrolment

01/04/2003

Date of final enrolment

01/04/2006

Locations

Countries of recruitment

United Kingdom

England

Study participating centre Transplant Unit

Papworth Everard

United Kingdom

CB3 8RE

Sponsor information

Organisation

Papworth Hospital NHS Trust (UK)

ROR

https://ror.org/01qbebb31

Funder(s)

Funder type

Industry

Funder Name

Novartis Pharmaceuticals (UK)

Results and Publications

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?
Abstract results	results presented at 24th International Society of Heart and Lung Transplantation	01/02 /2004		No	No
Abstract results	results presented at 25th International Society of Heart and Lung Transplantation	01/02 /2005		No	No