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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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