

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
Registration date 08/07/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 05/07/2018	Condition category Surgery	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pasupathy Sivasothy

Contact details
Transplant Unit
Papworth Hospital NHS Trust
Papworth Everard
United Kingdom
CB3 8RE

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 immunosuppression?

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