

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

<b>Submission date</b> 16/05/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 08/07/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 05/07/2018	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**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**

**Secondary identifying numbers**  
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

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

## 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 measure

Renal function at 3 months post transplant

**Secondary outcome measures**

Not provided at time of registration

**Overall study start date**

01/04/2003

**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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

90

**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  $\geq 170$  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**

England

United Kingdom

**Study participating centre**

**Transplant Unit**

Papworth Everard

United Kingdom

CB3 8RE

## **Sponsor information**

**Organisation**

Papworth Hospital NHS Trust (UK)

**Sponsor details**

Papworth Everard

Cambridge

England

United Kingdom

CB3 8RE

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/01qbebb31>

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Novartis Pharmaceuticals (UK)

## **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="#">Abstract results</a>	results presented at 24th International Society of Heart and Lung Transplantation	01/02/2004		No	No
<a href="#">Abstract results</a>	results presented at 25th International Society of Heart and Lung Transplantation	01/02/2005		No	No