

# A randomised prospective trial of daclizumab induction followed by sirolimus in association with mycophenolate mofetil and steroids versus standard cyclosporin based triple therapy for rejection prophylaxis in renal transplantation

<b>Submission date</b> 13/09/2005	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 17/10/2005	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/10/2016	<b>Condition category</b> Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

**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**

101177/ML17309

## **Study information**

**Scientific Title**

A randomised prospective trial of daclizumab induction followed by sirolimus in association with mycophenolate mofetil and steroids versus standard cyclosporin based triple therapy for rejection prophylaxis in renal transplantation

**Study objectives**

A calcineurin inhibitor (CNI) free regimen offers equivalent safety and efficacy to that of a CNI regimen and may offer improved long-term graft survival.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Liverpool Research Ethics Committee, 06/11/2002, ref: 02/07/124/A

**Study design**

Randomised controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

End stage renal failure patients undergoing renal transplantation.

**Interventions**

Cyclosporin, Mycophenolate Mofetil and steroids in the control arm of the trial.

Active arm patients received Sirolimus, Mycophenolate Mofetil, steroids and Daclizumab induction.

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Daclizumab, Sirolimus, Mycophenolate Mofetil, Cyclosporin

**Primary outcome(s)**

To determine whether a CNI free regimen provides improved renal function at 6 and 12 months post-transplant as compared with a conventional Cyclosporin based regimen in renal transplant patients. This will be assessed by comparing the differences in renal function between the

groups, as measured by a creatinine clearance (calculated glomerular filtration rate [GFR], Cockcroft & Gault).

### **Key secondary outcome(s))**

To compare the impact of a CNI free regime, if any, on:

1. Subsequent transplant outcome
2. Patient and graft survival
3. Infectious complications
4. Post-transplant malignancies

To compare the impact of a CNI free regime if any on:

1. Rejection rates at 6 & 12 months post-transplantation
2. Incidence and rate of recovery of post-transplant acute tubular necrosis
3. Incidence of drug-induced side-effects
4. Incidence and severity of post-transplant hypertension
5. Vascular endothelial growth factor (VEGF) expression in relation to graft survival and malignancy (Manchester data only)

### **Completion date**

24/06/2009

## **Eligibility**

### **Key inclusion criteria**

1. Patients must be over age 18
2. Patients must be recipients of a first, second or subsequent kidney transplant from a cadaveric or HLA mismatched live donor
3. Patients receiving a second or subsequent transplant must have maintained their primary graft for a minimum of 6 months, except if graft failure was due to technical reasons
4. Written informed consent
5. Women of childbearing potential must have a negative pregnancy test before commencing the trial and agree to use a medically acceptable method of contraception throughout the treatment period and for 3 months after discontinuing the trial

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

1. Known hypersensitivity to any of the study drugs
2. Prohibited prior or concomitant medications
3. Pregnant women or nursing mothers
4. White blood cell count (WBC) count  $<3000/\text{mm}^3$  or platelets  $<75,000/\text{mm}^3$  at time of study entry
5. Fasting cholesterol  $>7.8 \text{ mmol/l}$  or triglycerides  $>4.6 \text{ mmol/l}$
6. Human immunodeficiency virus (HIV) positive, Hepatitis B or C, history of alcoholism or drug abuse
7. Patients with known prior malignancies, except completely excised and localised non-melanoma skin cancers
8. Evidence of infiltrate, cavitation or consolidation on chest X-ray (CXR) obtained during pre-study screening
9. Recipients of marginal donor kidneys such as paediatric  $< \text{age } 2$ , terminal serum creatinine  $>220 \mu\text{mol/l}$ , preservation time  $>48$  hours, recipients of adult dual kidney transplants
10. Current participation in another trial or participation in another trial within the last 30 days
11. Highly sensitised recipients according to plasma renin activity (PRA)  $>50\%$
12. Any other concurrent cardiovascular, gastrointestinal, pulmonary or haematological conditions that would restrict the administration of Cyclosporin, Sirolimus, Mycophenolate, steroids or antilymphocytic agents, in the opinion of the Investigator

**Date of first enrolment**

26/11/2002

**Date of final enrolment**

10/06/2005

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

Royal Liverpool University Hospital

Liverpool

United Kingdom

L7 8XP

## Sponsor information

**Organisation**

Royal Liverpool Hospital NHS Trust (UK)

**ROR**

<https://ror.org/009sa0g06>

# Funder(s)

## Funder type

Industry

## Funder Name

Roche Products Limited (Ref: 00100674/14807)

## Funder Name

Wyeth

## Alternative Name(s)

## Funding Body Type

Private sector organisation

## Funding Body Subtype

For-profit companies (industry)

## Location

United States of America

# 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?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes