

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

Submission date 13/09/2005	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 17/10/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/10/2016	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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 measure

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).

Secondary outcome measures

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)

Overall study start date

26/11/2002

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

40 from each site - total of 80

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**

England

United Kingdom

Study participating centre
Royal Liverpool University Hospital
Liverpool
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Sponsor information

Organisation
Royal Liverpool Hospital NHS Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
<http://www.rlbuht.nhs.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

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