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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

Registration date
17/10/2005

Overall study status
Completed

Last Edited
11/10/2016

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Abdel Hammad

Contact details
9C Link
Renal Transplant Unit
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP
+44 (0)151 706 2664
abdul.hammad@rlbuht.nhs.uk

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

Primary study design
Interventional

Study design
Randomised controlled trial

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], Cockroft & Goult).

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/mm^3 or platelets <75,000/mm^3 at time of study entry
5. Fasting cholesterol >7.8 mmol/l or triglycerides >4.6 mmol/l
6. Human immunodeficiency virus (HIV) postitive, 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 < age 2, terminal serum creatinine >220 µmol/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