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Steroid Avoidance in Leeds with Alemtuzumab or Mycophenolate Mofetil (MMF) Immunosuppression

Submission date	Recruitment status	[X] Prospectively registered
28/02/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/03/2006	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/09/2013	Urological and Genital Diseases	

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
2006-000830-11

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

RL05/7239

Study information

Scientific Title

Acronym
SALAMI

Study objectives
To compare the efficacy of two tacrolimus based steroid avoidance regimes. This is an equivalence study with no anticipated difference in major endpoints between the two arms.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Leeds (East) Research Ethics Committee on the 26th July 2006 (ref: 06/Q1206/64, EudraCT No: 2006-000830-11).

Study design
Phase IV, open label, single centre, 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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Renal transplant immunosuppression

Interventions
Comparing two immunosuppression regimes:
1. Control (standard regime) - intra-operative Basiliximab and steroids followed by maintenance with Tacrolimus and MMF
2. Steroids intra-operative followed by Alemtuzumab then maintenence with Tacrolimus

Intervention Type

Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Basiliximab, Tacrolimus, MMF, Alemtuzumab

Primary outcome measure
Diethylene triamine pentaacetate (DTPA) isotopic glomerular filtration rate (GFR) at 12 months

Secondary outcome measures
1. Patient and graft survival
2. Incidence and duration of delayed graft function
3. Incidence and severity of steroid-treated presumptive and biopsy-confirmed acute rejection
4. Comparison of blood pressure control between groups by clinic readings, number of agents used and 24 hour monitoring at 6 and 12 months
5. Comparison of groups by pulse wave analysis, a powerful surrogate marker for cardiovascular outcome, at baseline, 6 and 12 months
6. Incidence of impaired glucose tolerance, weight gain and diabetes at 6 weeks, 6 and 12 months
7. Assessment of quality of life by questionnaires at 6 and 12 months
8. Assessment of adherence, looking at trough tacrolimus level variations between two groups
9. Economic analysis of the cost-effectiveness of both regimes
10. Comprehensive assessment of clinically indicated, implantation and one year protocol biopsies by:
10.1. Morphological scoring by Banff/chronic allograft damage index (CADI) system
10.2. Assessment of fibrosis by specific stains
10.3. Genomic analysis for products associated with ischaemia reperfusion, immune activation, inflammation and fibrosis
11. Analysis of urine and blood by proteomics at baseline, 3 months, 6 months, 12 months and other clinically indicated time points
12. Analysis of T cells for development of regulatory T cells
13. Analysis of anti-donor antibody responses
14. Monitoring of B and T cell subsets by flow cytometry
15. Monitoring of infectious complications/pathogens - including cytomegalovirus (CMV) infection and infections with polyomaviruses
16. Incidence of post transplant malignancies including post-transplant lymphoproliferative disease (PTLD)
17. Biochemical and haematological monitoring

Overall study start date
01/04/2006

Completion date
01/05/2008

Eligibility

Key inclusion criteria
1. Male and female patients who must be over age 18 years
2. Patients must be recipients of heart-beating cadaveric, non-heart beating or living donors

3. Patients receiving a 2nd or subsequent grafts 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 at risk of pregnancy 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. The manufacturer of Alemtuzumab advises effective contraception for 6 months after administration to men or women. Advice will be given to patients to discuss with the transplant medical staff if a pregnancy is planned.

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
120

Key exclusion criteria
1. Regional patients from Hull Royal Infirmary (due to the logistical difficulties in following these patients up from Leeds)
2. High Risk Recipients - defined as recipients who have one or more of the following: 2 human leukocyte antigen, type DR (HLA-DR) mismatch, previous immunologically mediated graft loss in less than 6 months, preoperative donor specific antibodies
3. Known hypersensitivity to the investigational medicinal product (IMP) including the standard drugs
4. Prohibited prior or concomitant medications
5. Pregnant women or nursing mothers
6. White blood cell count (WBC) count <3000/mm^3 or platelets <75,000/mm^3 at time of study entry
7. Any other concurrent cardiovascular, gastrointestinal, pulmonary or haematological conditions that would restrict the administration of study drugs in the opinion of the investigator

Date of first enrolment
01/04/2006

Date of final enrolment
01/05/2008

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Renal Unit
Leeds
United Kingdom
LS9 7TF

Sponsor information

Organisation
Leeds Teaching Hospitals NHS Trust (UK)

Sponsor details
Research and Development Dept.
6th Floor Wellcome Wing
Leeds General Infirmary
Great George Street
Leeds
England
United Kingdom
LS1 3EX

Sponsor type
Hospital/treatment centre

Website
http://www.leedsth.nhs.uk/sites/research_and_development/

ROR
https://ror.org/00v4dac24

Funder(s)

Funder type
Government

Funder Name
Leeds Teaching Hospitals NHS Trust (UK) - research fund

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?
Results article	results	01/04/2012		Yes	No
Results article	results	27/12/2013		Yes	No