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Trial to investigate the impact of haemodialysis before transplant surgery on early kidney allograft function

Submission date	Recruitment status	[_] Prospectively registered
03/04/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
20/04/2009	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
20/04/2009	Urological and Genital Diseases	[_] 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
N/A

Study information

Scientific Title
Randomised controlled trial evaluating the effect of haemodialysis applied before transplant surgery on early renal allograft function

Study objectives
1. Due to the pro-inflammatory effects of dialyser exposure pre-transplant haemodialysis adversely affects the evolution of early renal allograft function
2. Owing to its anti-inflammatory effects regional dialysis citrate anticoagulation improves early graft function

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Medical University of Vienna approved on the 30th June 2003 (ref: 151 /2003)

Study design
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

Health condition(s) or problem(s) studied
Kidney allograft function

Interventions
Based on pre-transplant levels of serum potassium (a concentration greater than 5.0 mEq/L is regarded as a requirement for pre-operative dialysis) patients are randomly assigned to one of two separate two-group parallel randomised controlled trials:
1. Patients presenting with a potassium less than or equal to 5.0 mEq/L are randomised to undergo haemodialysis versus no dialysis
2. Patients with a potassium greater than 5.0 mEq/L are randomised to receive anticoagulation during dialysis with heparin versus citrate

Patients assigned to pre-transplant haemodialysis receive treatment with a full-synthetic low-flux polysulfone membrane and a bicarbonate-buffered dialysate. Blood flow is adjusted to 200 to 400 ml/min and dialysate flow to 500 ml/min. Patients are dialysed for 3.0 hours without ultrafiltration.

Patients randomised to heparin anticoagulation receive an initial bolus of 1000 U of heparin followed by continuous infusion of 1000 U per hour. Patients allocated to citrate anticoagulation receive trisodium citrate at a rate of 25 - 50 mmol/h via the arterial line. Calcium is supplemented using a continuous infusion of half-molar calcium chloride solution into the venous return (initial starting dose 10 mmol/h). For citrate anticoagulation, a calcium-free dialysate is used. To keep systemic free calcium levels constant within +/- 10% of the baseline value calcium infusion rates are adjusted according to the results of regular monitoring of blood ionized calcium.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Estimated glomerular filtration rate (eGFR) at day 5 post-transplantation calculated according to the reexpressed Modification of Diet in Renal Disease (MDRD) study equation.

Secondary outcome measures
1. eGFR according to the Mayo Clinic equation at day 5
2. Serum creatinine level at day 5
3. Delayed graft function (need for dialysis within the first post-transplant week)
4. Slow graft function (definition: serum creatinine greater than 3 mg/dL on post-operative day 5 without requiring dialysis)
5. Acute biopsy-proven cell-mediated allograft rejection within the first three months
6. Acute C4d-positive graft dysfunction within the first three months
7. One-year actuarial death-censored graft survival

Overall study start date
02/07/2003

Completion date
18/09/2008

Eligibility

Key inclusion criteria
Adult (aged 18 years and over) male or female end-stage renal disease patients on maintenance haemodialysis anticipating deceased donor kidney allotransplantation.

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
220

Key exclusion criteria
1. Aged less than 18 years
2. Pre-emptive kidney transplantation
3. Non-heart-beating donor transplantation
4. Combined organ transplantation
5. Continuous ambulatory peritoneal dialysis as maintenance renal replacement therapy
6. Symptomatic fluid overload necessitating pre-operative ultrafiltration
7. Presensitised patients subjected to peri-transplant immunoadsorption for desensitisation
8. Patients subjected to haemodialysis less than 16 hours before randomisation

Date of first enrolment
02/07/2003

Date of final enrolment
18/09/2008

Locations

Countries of recruitment
Austria

Study participating centre
Division of Nephrology and Dialysis
Vienna
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Sponsor information

Organisation
Medical University of Vienna (Austria)

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Sponsor type
University/education

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ROR
https://ror.org/05n3x4p02

Funder(s)

Funder type
University/education

Funder Name
Medical University of Vienna (Austria)

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