

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

Submission date 03/04/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 20/04/2009	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/04/2009	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

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

Austria

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Sponsor information

Organisation

Medical University of Vienna (Austria)

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Sponsor type

University/education

Website

<http://www.meduniwien.ac.at>

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