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Does Lisinopril protect transplanted kidneys with chronic vascular rejection (CR) from progressive failure?

Submission date 02/09/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 09/09/2005	**Overall study status** Completed	
Last Edited 14/06/2011	**Condition category** Surgery	

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

1720

Study information

Scientific Title

Study objectives
Proteinuria and progression to end-stage renal failure are closely linked in patients with diseased native kidneys. ACE-inhibitors are known to reduce proteinuria and ameliorate the rate of decline of renal function. Data are lacking in kidney transplant patients with proteinuria and chronic allograft nephropathy (CAN). Do comparable beneficial effects of ACE-inhibitors also apply in transplant patients?

Publications resulting from small clinical studies were needed to design this trial as no previous data was available:
Rustom R et al: Effects of Angiotensin-converting-enzyme inhibitors (ACE-i) on progression to end-stage renal failure in chronic vascular rejection (CR). Transplantation Proceedings 2001, 33: 1175-1176.
Rustom R et al: Renal tubular peptide catabolism, injury & ammonia excretion in patients with chronic vascular rejection: effects of Lisinopril. Renal Failure 2001, 23:517-531.
Bone JM, Amara AB, Shenkin A, Hammad A, Sells RA, Alexander J, McArdle F, Rustom R: Calcineurin inhibitors and proximal renal tubular injury in renal transplant patients with proteinuria and chronic allograft nephropathy. Transplantation 2005, 79:119-122.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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

Health condition(s) or problem(s) studied
End-stage renal failure

Interventions
Use of Lisinopril in the active limb only (dose used titrated in individual patients to achieve maximum reduction in proteinuria without leading to postural hypotension).
Control: usual care
There is very close attention to detail and all patients regardless of which limb in the trial have strict blood pressure control, as well as treatment of their anaemia, metabolic acidosis and secondary hyperparathyroidism.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Lisinopril

Primary outcome measure
Preservation of glomerular filtration rate (GFR) ml/min.

Secondary outcome measures
1. Reduction in proteinuria
2. Sub-group analyses:
2.1 Effects on tubular metabolism of aprotinin (lisinopril limb only)
2.2 Urinary NAG, MCP-1, TGF-Beta
2.3 Plasma markers of oxidative stress
2.4 ACE genotyping

Overall study start date
01/09/2000

Completion date
30/09/2006

Eligibility

Key inclusion criteria
1. Biopsy proven CAN at least 6 months post kidney transplantation - both cadaveric and live-related. Each biopsy will be independently examined and the severity graded by an experienced pathologist
2. Not on ACE-inhibitor (or angiotensin II antagonists) treatment
3. Patients may be on any combination of immunosuppressive therapy. However, those who have been converted to tacrolimus or mycophenolate mofetil after diagnosis of CAN within 6 months are excluded
4. Proteinuria of more than 1.0 g/24 hours
5. Mean creatinine clearance >20 ml/min
6. No history of a transient ischaemic or cardiovascular event or malignancy in the last 6 months
7. Patients aged between 18-70 years

Participant type(s)

Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
70 Years

Sex
Both

Target number of participants
42

Key exclusion criteria
1. Patients with clinical or histological evidence or acute rejection in the last 3 months
2. Patients with evidence of renal artery stenosis
3. Persistently high cyclosporin or tacrolimus levels
4. Abnormal liver function tests
5. Pregnant or ineffective contraception
6. Chronic intractable cough

Date of first enrolment
01/09/2000

Date of final enrolment
30/09/2006

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
School of Clinical Science
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Sponsor information

Organisation
Royal Liverpool and Broad Green University Hospitals 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
University/education

Funder Name
Mersey Kidney Research (Ref No: R1975/1) (UK)

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	15/01/2010		Yes	No