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Erythopoietin and delayed graft function in renal allografts from extended criteria donors

Submission date 07/07/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/08/2009	**Overall study status** Completed	
Last Edited 04/02/2015	**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
10322

Study information

Scientific Title
Erythopoietin and delayed graft function in renal allografts from extended criteria donors: a single centre, randomised, double blind, parallel-group, placebo controlled trial

Acronym
EPOTRIAL

Study objectives
The principal objective of this study is to investigate whether giving erythropoietin (EPO) to recipients at the time of kidney transplantation will significantly alter the gene expression and protein levels of known biomarkers of ischaemia/reperfusion injury compared to patients receiving placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Central Manchester Research Ethics Committee approved on the 25th July 2007 (ref: 07/Q1407/94)

Study design
Single centre randomised double blind parallel-group placebo 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 transplantation

Interventions
During implantation of the kidney, after the vascular anastamosis, but prior to clamp release, an intravenous bolus dose of EPO (33,000 iu) or placebo will be administered by the anaesthetist through the central line immediately before the surgeon opens the clamps to allow blood flow into the kidney. An intravenous bolus dose of EPO (33,000 iu) or placebo will be administered to the patient 24 hours and 48 hours following the first 'in surgery' dose.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
Comparison of plasma and urine levels of biomarkers of acute kidney injury (NGAL, IL-18, HGF, FABP1) between the treatment and placebo groups during the immediate post-operative period

Secondary outcome measures
1. Comparison of the incidence and severity of delayed graft function and acute rejection between the two arms of the study in the early post-operative period
2. Kidney function using standard clinical parameters will be monitored post-operatively, and at 3, 6, 9 and 12 months

Overall study start date
01/09/2007

Completion date
30/06/2010

Eligibility

Key inclusion criteria
1. Men and women aged greater than or equal to 18 years
2. The subject is willing to provide signed written informed consent
3. The subject is the recipient of a deceased donor kidney transplant
4. The donor and/or donor kidney meet at least one of the following extended criteria for organ donation from either 4.1. or 4.2. as described below:
4.1. Donor:
Greater than 50 years with:
4.1.1. Cerebrovascular accident (CVA) + hypertension (HTN) + serum creatinine (SCr) greater than 1.5
4.1.2. CVA + HTN
4.1.3. CVA + SCr greater than 1.5
4.1.4. HTN + SCr greater than 1.5
Greater than 60 years with:
4.1.5. CVA
4.1.6. HTN
4.1.7. SCr greater than 1.5
4.2. Additional criteria cold ischaemia time (CIT) greater than or equal to 24 hours

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Women who are pregnant or breastfeeding
2. Women with a positive pregnancy test on enrolment
3. Subjects with any active infection that would normally exclude transplantation
4. Subjects who have used any other investigational drug within 30 days prior to transplantation
5. Subjects with a haemoglobin level greater than or equal to 15 g/dl
6. Subjects with a diastolic blood pressure greater than 100 mmHg pre-transplantation
7. Subjects previously intolerant of NeoRecormon®

Date of first enrolment
01/09/2007

Date of final enrolment
30/06/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Department of Nephrology
Manchester
United Kingdom
M13 9WL

Sponsor information

Organisation
Central Manchester and Manchester Children's University Hospital (CMMCUH) NHS Trust (UK)

Sponsor details

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Sponsor type
Hospital/treatment centre

Website
http://www.cmft.nhs.uk/

ROR
https://ror.org/00he80998

Funder(s)

Funder type
Government

Funder Name
Roche (UK) (ref: Neo 034)

Alternative Name(s)
F. Hoffmann-La Roche Ltd, F. Hoffmann-La Roche & Co, F. Hoffmann-La Roche AG, Roche Holding AG, Roche Holding Ltd, Roche Holding, Roche Holding A.G., Roche Holding, Limited, F. Hoffmann-La Roche & Co.

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
Switzerland

Funder Name
Central Manchester and Manchester Children's University Hospital (CMMCUH) NHS Trust (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	03/02/2015		Yes	No