

# Erythropoietin and delayed graft function in renal allografts from extended criteria donors

<b>Submission date</b> 07/07/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 19/08/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 04/02/2015	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**Protocol serial number**  
10322

## Study information

**Scientific Title**  
Erythropoietin 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)

**Primary study design**

Interventional

**Study design**

Single centre randomised double blind parallel-group placebo controlled trial

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Renal transplantation

**Interventions**

During implantation of the kidney, after the vascular anastomosis, 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(s)**

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

**Key secondary outcome(s)**

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

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

All

**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**

United Kingdom

England

**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)

**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., Roche Holdings, Inc.

### 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

### Individual participant data (IPD) sharing plan

#### IPD sharing plan summary

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	03/02/2015		Yes	No