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The use of erythropoietin in cardiac surgery to protect against ischaemia-related injury in kidney and other organ systems

Submission date 08/05/2006	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 02/06/2006	**Overall study status** Completed	
Last Edited 16/12/2013	**Condition category** Circulatory System	

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
ajmepo1

Study information

Scientific Title

Acronym
EPOCARD

Study objectives
To investigate whether pre-treatment with erythropoietin (EPO) reduces the incidence of renal injury associated with surgery under cardiopulmonary bypass.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval details not yet received as of 02/06/06.

Study design
Prospective, randomised, double-blind, placebo controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Prevention

Participant information sheet

Health condition(s) or problem(s) studied
Ischaemic heart disease

Interventions
Erytropoietin versus placebo in coronary artery bypass graft surgery

Intervention Type
Drug

Phase
Not Specified

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

Primary outcome measure
Change in creatine calculated clearance between preoperative baseline and postoperative day one

Secondary outcome measures
1. Oliguria
2. Acute renal failure requiring dialysis
3. Urinary analysis of N-acetyl-BD-glucosaminidase and alpha-1 microglobulin/creatinine ratio
4. Evidence of cardiac injury (troponin I)
5. Neurological injury S-100
6. Evidence of type I neurological outcome (stroke, transient ischaemic attack [TIA])
7. Type II neurological outcome (new deterioration in intellectual function, confusion, agitation, disorientation, memory deficit or seizure)

Overall study start date
01/10/2006

Completion date
01/10/2007

Eligibility

Key inclusion criteria
1. First-time coronary artery bypass surgery
2. Age >70
3. Serum creatinine >120 µmol/l
4. Diabetes mellitus (diet or medication controlled)

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
84

Key exclusion criteria
1. Hypersensitiviy to mammalian cell-derived products to (human) albumin, to EPO or any of the ingredients of EPO
2. Hypercoagulability
3. Significant psychiatric or neurological disease that would prevent adherence to the requirements of the protocol
4. Immunosuppression immunocompromised (including, but not limited to aquired immune deficiency syndrome (AIDS) and immunosuppressive therapy)
5. Significant hepatic disturbance
6. Chronic renal impairment (requiring haemodialysis or peritoneal dialysis)

7. Pregnant or breast feeding
8. Current treatment with human recombitant erythropoietin
9. Previous cardiac surgery

Date of first enrolment
01/10/2006

Date of final enrolment
01/10/2007

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Scottish Cardiopulmonary Transplant Unit
Glasgow
United Kingdom
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Sponsor information

Organisation
NHS Greater Glasgow and Clyde (UK)

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Sponsor type
Government

ROR
https://ror.org/05kdz4d87

Funder(s)

Funder type
Industry

Funder Name
Roche Products Limited (NEO 029)

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