ISRCTN41687085 https://doi.org/10.1186/ISRCTN41687085

A randomised, open label controlled trial of Epoetin Beta in the treatment of anaemia post-transplantation

Submission date 16/08/2006	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 03/10/2006	**Overall study status** Completed	
Last Edited 06/01/2021	**Condition category** Haematological Disorders	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2006-003502-26

Protocol serial number
ESA - 1

Study information

Scientific Title
A randomised, open label controlled trial of Epoetin Beta in the treatment of Anaemia Post-Transplantation

Acronym
Epoetin Beta in PTA

Study objectives
The treatment of post-transplant anaemia with epoetin beta decreases the rate of decline of kidney function and the quantity of proteinuria. It also affects markers of cardiovascular disease, endothelial dysfunction and tubular damage, and blood pressure control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Submitting in August 2006 to East London and the City Health Authority Ethics Committee.

Study design
Randomised controlled open trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-transplant anaemia

Interventions
Treatment with epoetin beta.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Epoetin Beta

Primary outcome(s)
1. Rate of decline of glomerular filtration rate (GFR)
2. Change in blood pressure control
3. Change in quantity of proteinuria

Key secondary outcome(s))
1. Change in left ventricular hypertrophy (LVH) as measured on echocardiogram
2. Change in intimal and medial wall thickness as determined by intimal medial thickness and

flow dependant vasodilation as determined by ultrasound
3. Changes in functional quality of life scores
4. Changes in markers of tubular damage in the urine
5. Changes in markers of endothelial dysfunction

Completion date
30/09/2009

Eligibility

Key inclusion criteria
1. Male and female patients greater than three months post-kidney transplant
2. Haemoglobin less than 11.5 g/dl and greater than 9.0 g/dl
3. Age greater than 18 years of age and less than 85 years of age

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
55

Key exclusion criteria
1. Current treatment with an erythropoiesis stimulating agent (ESA)
2. Uncontrolled hypertension
3. Congestive cardiac failure (New York Heart Association [NYHA] grade III and IV)
4. History of seizures
5. History of thombotic episodes
6. Pregnancy
7. Lactation
8. Presence of systemic disease, infection or inflammatory conditions
9. Hepatic insufficiency
10. Active hepatitis
11. Uncontrolled hypothyroidism
12. Chronic alcoholism
13. Known hypersensitivity to the active substance in the cartridge or benzoic acid
14. Known sensitivity to Epoetin Beta

Date of first enrolment

01/10/2006

Date of final enrolment
30/09/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Kidney Medicine and Transplantation
London
United Kingdom
E1 1BB

Sponsor information

Organisation
Barts and the London NHS Trust (UK)

ROR
https://ror.org/00b31g692

Funder(s)

Funder type
Industry

Funder Name
Roche Products Ltd (UK) - provided an educational grant though the Joint Research Department for the salary of the Research Fellow

Results and Publications

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	01/02/2020	06/01/2021	Yes	No