

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
Registration date 03/10/2006	Overall study status Completed	☐ Protocol
Last Edited 06/01/2021	Condition category Haematological Disorders	☐ Statistical analysis plan
		☒ Results
		☐ 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

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.

Primary study design

Interventional

Study design

Randomised controlled open trial

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 thrombotic 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 through 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