

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	<input type="checkbox"/> Prospectively registered
Registration date 03/10/2006	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/01/2021	Condition category Haematological Disorders	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

2006-003502-26

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Post-transplant anaemia

Interventions

Treatment with epoetin beta.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Epoetin Beta

Primary outcome measure

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

Secondary outcome measures

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

Overall study start date

01/10/2006

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

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

England

United Kingdom

Study participating centre

Department of Kidney Medicine and Transplantation

London

United Kingdom

E1 1BB

Sponsor information

Organisation

Barts and the London NHS Trust (UK)

Sponsor details

Joint Research and Development Office

3rd Floor Rutland House

42-46 New Street

Whitechapel

London
England
United Kingdom
E1 2AX
+44 (0)20 7882 7250
Gerry.Leonard@bartsandthelondon.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.bartsandthelondon.nhs.uk/research>

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

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