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The effect of treating patients with anaemia in diabetic nephropathy to different target haemoglobin levels with epoetin beta

Submission date	Recruitment status	[ ] Prospectively registered
17/10/2006	Stopped	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/12/2006	Stopped	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
09/02/2009	Haematological Disorders	[ ] Record updated in last year

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
ESA-2

Study information

Scientific Title

Study objectives
That treating patients with anaemia in diabetic nephropathy to a higher haemoglobin target range decreases rate of decline of renal function, requirement for dialysis, doubling of creatinine and death.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Randomised controlled open trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Anaemia in diabetic nephropathy

Interventions
All patients should be iron replete (i.e. ferritin 0.1 or Tsats 0.2%) before randomisation. Participants will be given intravenous (IV) iron to replete iron stores if required before randomisation.

Participants will be randomised to two target ranges of haemoglobin on a 1:1 basis. Target ranges:
1. Hb 10.5 - 12 g/dl
2. Hb 12.1 - 13.5 g/dl

Participants will be treated with Epoetin Beta subcutaneously, if required, to maintain their haemoglobin within the target group. This will be a starting dose of 50 units/kg/week given once a week. Dose will be titrated on a monthly basis to start with, and then modified according to response (total dose 720 units/kg/week). Participants will be treated for three years.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome(s)
1. Rate of decline of renal function as determined by estimated glomerular filtration rate (GFR)
2. Composite end-point of:

2.1. Doubling of creatinine
2.2. Reaching end-stage renal failure
2.3. Death

Key secondary outcome(s))
1. Change in left ventricular hypertrophy as measured on echocardiogram
2. Change in intimal and medial wall thickness as determined by intimal thickness and flow dependant vasodilation as determined by ultrasound
3. Change in functional quality of life scores
4. Change in markers of endothelial dysfunction
5. Change of markers of tubular damage in the urine

Completion date
30/11/2009

Reason abandoned (if study stopped)
Objectives no longer viable

Eligibility

Key inclusion criteria
1. Male and female patients with diabetic nephropathy and chronic kidney disease III and IV
2. Age more than 18 years and less than 80 years
3. Haemoglobin less than 11.5 g/dl

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Key exclusion criteria
1. Current treatment with an erythropoiesis-stimulating agent (ESA)
2. Uncontrolled hypertension
3. Congestive cardiac failure
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
01/12/2006

Date of final enrolment
30/11/2009

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Department of Kidney and Tranpslant Medicine
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 Pharmaceuticals (UK) - salary of research doctor through the hospital Research and Develpment Department (ref: ML20597)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration