

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

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

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

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

Primary study design

Interventional

Study design

Randomised controlled open trial

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 Transplant 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 Development Department (ref: ML20597)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration