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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 [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/12/2006	**Overall study status** Stopped	
Last Edited 09/02/2009	**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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet

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 measure
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

Secondary outcome measures
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

Overall study start date
01/12/2006

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
Both

Target number of participants
160

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
England

United Kingdom

Study participating centre
Department of Kidney and Tranpslant Medicine
London
United Kingdom
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Sponsor information

Organisation
Barts and the London NHS Trust (UK)

Sponsor details
Research and Development Office
3rd Floor Rutland House
42-46 New Road
Whitechapel
London
England
United Kingdom
E1 2AX

Sponsor type
Hospital/treatment centre

Website
http://www.bartsandthelondon.org.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

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