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Influence of erythropoietin simulating agents and iron therapy on HbA1c

Submission date	Recruitment status
29/04/2010	No longer recruiting
Registration date	**Overall study status**
12/05/2010	Completed
Last Edited	**Condition category**
16/02/2011	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

Protocol serial number
08/H1304/114

Study information

Scientific Title
The effect on HbA1c in patients with diabetes mellitus when receiving either intravenous or erythropoietin stimulating agent therapy: a prospective follow-up study

Study objectives
The fall in HbA1c seen in patients with diabetes mellitus upon receiving either intravenous or erythropoietin stimulating agent therapy is independent of any change in glycaemic control.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hull and East Riding Local Research Ethics Committee Research Ethics Office approved on the 16th January 2009 (ref: 08/H1304/114)

Study design
Prospective follow up study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Diabetes mellitus/chronic kidney disease

Interventions
This was a prospective study of patients with T2DM and CKD stage IIIB or IV (estimated glomerular filtration rate MDRD 15 - 44 ml/min/1.73 m^2) selected for treatment with intravenous iron and/or erythropoietin stimulating agents between January 2009 and December 2009 inclusive. All patients were attending a single renal service where the decision to commence iron and ESA therapy was made by the attending physician.

The study consisted of two groups. The first group (A) were patients selected for iron therapy according to clinical need and the second group (B) of patients were those needing ESA treatment.

Iron Therapy Group (A):
All patients selected for iron therapy had either absolute or functional iron deficiency as evidenced by serum ferritin values less than 200 µg/L. All patients had haemoglobin less than or equal to 10.5 g/dl. Patients in this group were not on previous or concurrent ESA therapy and were vitamin B12 and folate replete.

Erythropoietin stimulating agent (ESA) therapy Group (B):
All patients receiving ESA therapy had haemoglobin less than or equal to 10.5 g/dl and were considered iron, vitamin B12 and folate replete prior to initiation. Patients were considered iron replete following a serum ferritin value greater than 200 µg/L or having received intravenous iron at least 6 weeks prior to ESA therapy.

Sample analysis and monitoring of glycaemic control:
Patients in groups A and B were provided with the Abbott Freestyle Freedom Lite glucose sensor (Abbott Diagnostics, Maidenhead, UK). Patients were requested to perform 7 point glucose monitoring (7PGM) 3 times weekly one month before commencement of treatment until the end of the study. 7PGM was defined as pre-meal, 90 min post-meal and pre-bed capillary glucose measurements.

Continuous glucose monitoring (CGMS) was performed using the Medtronic CGMS Ipro Continuous Glucose Recorder (Medtronic Minimed, Northridge, US). Using this system,

measurements of interstitial glucose levels were made 228 times over a 24 hour period. This was done in parallel with patient 7PGM over the period of CGMS to allow accurate correlation of glycaemic control. All patients had CGMS performed for at least 2 days prior to ESA therapy and once again at the end of the study.

Results from the 7PGM and CGMS were downloaded from their respective meters for data analysis. Results from the CGMS included at least a successful 24 hour profile over the monitoring period with no gaps greater than 120 mins.

The management of diabetes control were left to the patients and their health care professional. Treatment for glycaemic control was monitored throughout the study period.

Blood was drawn fasting from all patients for HbA1c and full blood profile. Patients in group A and B had samples taken at the one month before commencement of therapy and once again 4 months following treatment initiation.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
To study HbA1c changes in relation to mean blood glucose over study period, measured 1 month before treatment initiation and 4 months after.

Key secondary outcome(s))
Measured 1 month before treatment initiation and 4 months after:
1. To study HbA1c changes in relation to haemoglobin and haematocrit levels
2. To relate fructosamine, glycated albumin and 1,5 anhydroglucitol with changes in mean blood glucose

Completion date
01/06/2010

Eligibility

Key inclusion criteria
1. Patients with established chronic kidney disease (stage III - IV) (estimated glomerular filtration rate [eGFR] using Modification of Diet in Renal Disease [MDRD] 15 - 59 mL/min/1.73 m^2) who are to undergo iron and/or erythropoiesis stimulating agent (ESA) therapy
2. Patients who have established diabetes mellitus - both type I and II
3. Patients with no prior diagnosis of diabetes mellitus (control group)
4. Aged 18 to 80 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Patients who not have renal failure (CKD stage I and II)
2. Patients who are unable or do not wish to give consent
3. Patients with currently investigated for potential blood loss
4. Patients with a haematological malignancy/haemolysis
5. Patients with known haemaglobinopathy
6. Patient with significant liver disease (prothrombin time [PT] greater than 16)
7. Patients with a diagnosis of myeloma
8. Patients with severe hyperparathyroidism (parathyroid hormone [PTH] greater than 800 picograms/ml)

Date of first enrolment
01/02/2009

Date of final enrolment
01/06/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
220 - 226 Anlaby Road
Hull
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Sponsor information

Organisation
Hull and East Yorkshire Hospitals NHS Trust (UK)

ROR

https://ror.org/01b11x021

Funder(s)

Funder type
University/education

Funder Name
Hull York Medical School (UK) - Michael White Research Department

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	01/11/2010		Yes	No