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Survey of the current management of secondary hyperparathyroidism (SHPT) in patients with end-stage renal disease undergoing dialysis in the UK NHS

Submission date
28/10/2013

Recruitment status
No longer recruiting

Registration date
11/12/2013

Overall study status
Completed

Last Edited
04/04/2022

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
End-stage renal disease (ESRD) or chronic kidney disease occurs when the kidneys have lost all or almost all of their ability to filter excess fluid and waste products from the body. Almost all patients with ESRD also have secondary hyperparathyroidism (SHPT), which is the excessive release of parathyroid hormone (PTH) by the parathyroid glands (small glands in the neck) in response to low blood calcium levels and abnormal growth of these glands. SHPT causes calcium levels to rise and phosphorus levels to fall, leading to abnormal levels in a patients blood. Uncontrolled SHPT is associated with an increased risk of death in patients with ESRD. However, currently there is no data available about what happens when control is achieved for a number of markers of the disease (which include levels of calcium and phosphorus) within the same patient. In addition there is limited knowledge of the patterns of how SHPT is treated in normal clinical practice and their associated treatment costs. This study aims to describe the management of secondary hyperparathyroidism (SHPT) in the UK NHS with a focus on the renal unit service structure and policies, treatments, prescribing patterns and the costs and outcomes achieved. SHPT management will be explored in reference to the existing UK Renal Association Clinical Guidelines, the National Kidney Federation Kidney Disease Outcome Quality Initiative (KDOQI) guidelines and the Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline. There are a number of medications available to physicians to control the levels of the disease markers. However, currently there is limited availability of both the medication cinacalcet (a drug that mimics the action of calcium with body tissues) and also a group of medications known as non-calcium containing phosphate binders. There is a perception that this availability varies considerably from hospital to hospital due to local funding policies. As such, there is an interest in understanding what triggers a physician to prescribe cinacalcet and non-calcium containing phosphate binders in the UK.

Who can participate?
Patients currently undergoing haemodialysis or peritoneal dialysis (types of treatments for kidney

failure) are eligible for participation. Patients are not eligible if they have been undergoing dialysis for less than 90 days at the start of data collection.

What does the study involve?
Data will be collected from medical records of patients and through review of written Trust / department policies and staff complement / staffing structure / organisational diagram documents. Data about the clinical management of patients will be extracted from renal unit databases and paper-based medical records.

What are the possible benefits and risks of participating?
Patients will not participate directly in this study. Inclusion of a patients medical records in this review will cause no additional risk for the patient, as their inclusion involves no further diagnosis, assessment or therapeutic practice other than that considered appropriate by his/her physician. As patients are not directly participating in the study, there are no direct benefits. However, it is anticipated that their data will help to improve care and patient outcomes for SHPT.

Where is the study run from?
Data will be collected from Renal Units in Addenbrookes Hospital, Cambridge; Birmingham Heartlands Hospital; Doncaster Royal Infirmary; Freeman Hospital, Newcastle; Ninewells Hospital, Dundee; Northern General Hospital, Sheffield; Royal Devon and Exeter Hospital and Southend Hospital. The Chief Investigator (Dr Nicholas Pritchard) is based at Addenbrookes Hospital, Cambridge.

When is study starting and how long is it expected to run for?
The study started in June 2011 and finished in November 2011.

Who is funding the study?
Amgen sponsored this research study.

Who is the main contact?
Dr Nicholas Pritchard
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Contact information

Type(s)
Scientific

Contact name
Dr Nicholas Pritchard

Contact details
Addenbrookes Hospital
Hills Road
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Additional identifiers

Protocol serial number
20090260

Study information

Scientific Title
A cross-sectional survey of the current management of secondary hyperparathyroidism in patients with end-stage renal disease undergoing dialysis in the UK NHS

Study objectives
There were no hypotheses for this study, as this was an observational study. SHPT has a considerable impact on the morbidity and mortality of patients with end-stage renal disease. Although the UK Renal Registry report provides comprehensive data on achievement of single markers of disease control there is no data available that describes achievement of multiple markers of disease control within the same patient; it might be argued that this is a more important measure. Similarly, longitudinal data describing achievement of disease marker targets is not available. In addition there is limited knowledge regarding the patterns of treatment for SHPT in normal clinical practice and their associated treatments costs. Currently there is restricted availability of both cinacalcet and non-calcium containing phosphate binders with a perception that this availability differs widely from renal unit to renal unit due to local funding policies. There is interest in understanding the triggers for prescription of cinacalcet and non-calcium containing phosphate binders in the UK in terms of clinical and treatment history.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee East of England - Cambridge South, 11/03/2011, REC refrence number: 11/EE /0043

Primary study design
Observational

Study design
Observational retrospective multi-centre cross-sectional survey in secondary care

Study type(s)
Other

Health condition(s) or problem(s) studied
Secondary hyperparathyroidism

Interventions
Data regarding renal unit service structure and local policies relating to SHPT management were obtained through review of written Trust/department policies and staff complement /staffing structure/organisational diagram documents. Data regarding the clinical management of patients was extracted from renal unit databases and paper-based medical records. All data was sourced from written policy and staffing documents or the hospital Trust computer systems and

patients hospital medical notes in the hospital Trusts. No treatment was given, and there was no direct contact with patients. The period of data collection / observation was between 6th June 2011 to 22 November 2011 (twenty-five weeks).

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
As of 31/10/2017:
% patients with all stipulated biochemical markers within target range according to:
• UK Renal Association Clinical Guidelines
• KDOQI Guidelines
• KDIGO Clinical Practice Guideline

Prior to 31/10/2017:
N/A - observational study

Key secondary outcome(s)
As of 31/10/2017:
% patients with all stipulated biochemical markers within 25%, 50%, 100% of target range, and more than 100% outside target range, according to:
• UK Renal Association Clinical Guidelines
• KDOQI Guidelines
• KDIGO Clinical Practice Guideline

% patients with all stipulated biochemical markers within target range at date of data collection and at 3 months prior to data collection according to:
• UK Renal Association Clinical Guidelines,
• KDOQI Guidelines,
• KDIGO Clinical Practice Guideline

Achievement of UK Renal Association Guideline targets (single, dual)
Achievement of KDOQI Guideline targets (single, dual, triple)
Achievement of KDIGO Guidelines targets (single, dual)
Description of services and policies related to SHPT management:
• Number of whole time equivalent consultant renal physicians per 100 dialysis patients
• Number of whole time equivalent junior doctors per 100 dialysis patients
• Number of whole time equivalent dietitians per 100 dialysis patients
• Number of whole time equivalent bone disease specialist nurses per 100 dialysis patients
• Number of whole time equivalent renal pharmacists per 100 dialysis patients
• Number of whole time equivalent surgeons who conduct parathyroidectomies per 100 dialysis patients
• Hospital guidelines used to shape clinical practice
• Hospital policy regarding availability of cinacalcet
• Hospital policy regarding availability of non-calcium containing phosphate binder
• Hospital policy regarding parathyroidectomy
o Proportion of patients having had parathyroidectomy
o Distribution of numbers of parathyroidectomies conducted

o Numbers total vs. partial parathyroidectomies
Reasons for repeat parathyroidectomy
Description of prescribing patterns for SHPT
• % of patients prescribed each drug and dose
• Mean (s.d.) cost of drug per patient

Clinical and prescribing pathway prior to initiation of non-calcium containing phosphate binders
• Mean (s.d.) adjusted calcium prior to initiation of non-calcium containing phosphate binders
• Mean (s.d.) phosphate prior to initiation of non-calcium containing phosphate binders
• Mean (s.d.) PTH prior to initiation of non-calcium containing phosphate binders
• Distribution of drug regimens for the 6 months preceding prescribing of non calcium-containing phosphate binders

Clinical and prescribing pathway prior to initiation of cinacalcet
• Mean (s.d.) adjusted calcium prior to initiation of cinacalcet
• Mean (s.d.) phosphate prior to initiation of cinacalcet
• Mean (s.d.) PTH prior to initiation of cinacalcet
• Distribution of drug regimens for the 6 months preceding prescribing of cinacalcet
• Proportion patients with parathyroidectomy in the 6 months preceding prescribing of cinacalcet

Clinical and prescribing pathway prior to parathyroidectomy:
• Mean (s.d.) adjusted calcium prior to parathyroidectomy
• Mean (s.d.) phosphate prior to parathyroidectomy
• Mean (s.d.) PTH prior to parathyroidectomy
• Distribution of drug regimens for the 6 months preceding parathyroidectomy

Prior to 31/10/2017:
N/A - observational study

Completion date
22/11/2011

Eligibility

Key inclusion criteria
1. Patients undergoing haemodialysis or peritoneal dialysis with a PTH greater than 15pMol for at least one reading in the 12 months prior to the data collection period.
2. Patients with a PTH 15pMol or less who have been prescribed a phosphate binder within the 12 months prior to the data collection period.

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex

All

Key exclusion criteria
Patients undergoing dialysis for less than 90 days prior to the data collection period.

Date of first enrolment
06/06/2011

Date of final enrolment
22/11/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Addenbrooke's Hospital
Cambridge
United Kingdom
CB2 2QQ

Sponsor information

Organisation
Amgen Limited (UK)

ROR
https://ror.org/02gvvc992

Funder(s)

Funder type
Industry

Funder Name
This trial was sponsored by Amgen UK and Ireland (study number: 20090260).

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as the data were collected for the specific purpose of the current study and should not be used for any other purpose.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results		31/10/2017	31/10/2017	No	No
Plain English results		14/11/2017	14/11/2017	No	Yes