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Cinacalcet, effects on cardiovascular and bone health in chronic kidney disease (CKD)

Submission date	Recruitment status	[ ] Prospectively registered
24/04/2008	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
31/07/2008	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
06/05/2016	Nutritional, Metabolic, Endocrine	[ ] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
2006VAS23

Study information

Scientific Title
A randomised controlled trial to examine the effects of calcimimetic therapy on bone and cardiovascular health in end-stage renal disease

Study objectives
Null hypothesis: Cinacalcet will have no effect on the change of bone and cardiovascular parameters, compared to standard therapy, in haemodialysis patients over a 12 month period.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Salford and Trafford Local Research Ethics Committee, approved in November 2005 (ref: 05 /Q1404/216)

Study design
Multi-centre randomised open-label interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Patients with uncontrolled secondary hyperparathyroidism and who are on haemodialysis

Interventions
Intervention arm: Cinacalcet (oral) alongside standard therapy. Dose of cinacalcet will be adjusted according to PTH and calcium, within the range of 30-180 mg daily.
Control arm: Standard therapy alone.

Standard therapy includes vitamin D analogues and all available phosphate binders.

Duration of interventions: 12 months

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cinacalcet

Primary outcome measure
The change of calcification score between the 2 cohorts at baseline and 12 months

Secondary outcome measures
The change in the following will be compared between the 2 arms at baseline and 12 months:
1. Vascular stiffness
2. Cardiac morphology
3. Cardiac function
4. Bone mineral density
5. Carotid Intima Media Thickness (CIMT)
6. Serum markers

Overall study start date
01/08/2006

Completion date
01/07/2009

Eligibility

Key inclusion criteria
1. Age 18-75 at recruitment, both male and female
2. On haemodialysis for >90 days
3. Parathyroid hormone (PTH) >=300 pg/ml
4. Corrected calcium >=2.1 mmol/l

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
75 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Atrial fibrillation
2. Any contra-indications to magnetic resonance (MR) scan or ability to cooperate with scan
3. Any factors which will influence computed tomography (CT) scan e.g. artificial heart valves, previous sternotomy wires, stents
4. Contra-indication to cinacalcet e.g., pregnant, breast feeding, known reaction
5. Moderate to severe liver disease (alanine transaminase [ALT] >3x normal)
6. Have a poor record of compliance with medication
7. Have participated in a study involving an investigational drug during the 30 days prior to the first visit
8. Be involved in any other research study which exposes the patient to radiation above that of normal clinical practice

Date of first enrolment
01/08/2006

Date of final enrolment
01/07/2009

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
H4 Renal Department
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
Salford Royal NHS Foundation Trust (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.srht.nhs.uk

ROR
https://ror.org/019j78370

Funder(s)

Funder type
Industry

Funder Name
Amgen, educational grant (USA)

Funder Name
University of Manchester, Translational Imaging Unit grant (UK)

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