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

Protocol serial number

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 /O1404/216)

Study design

Multi-centre randomised open-label interventional study

Primary study design

Interventional

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

75 years

Sex

All

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

United Kingdom

England

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

Sponsor information

Organisation

Salford Royal NHS Foundation Trust (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

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?

Participant information sheet 11/11/2025 No Yes