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Vitamin D levels in chronic kidney disease (CKD)

Submission date	Recruitment status	[_] Prospectively registered
29/04/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
29/04/2010	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/08/2016	Urological and Genital Diseases	[_] 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
6247

Study information

Scientific Title
Vitamin D in children with chronic kidney disease (CKD) on dialysis: a non-randomised interventional treatment pilot study

Study objectives
The aim of chronic kidney disease mineral and bone disorder (CKD-MBD) management is to maintain normal bone turnover and minimise vascular calcification. Recommendations to achieve this hinge on manipulation of parathyroid hormone (PTH) levels into a specified range using diet, preparations that prevent the absorption of phosphate and the activated form of

vitamin D (1-alpha hydroxycholecalciferol or alfacalcidol). However, there is no evidence base for this practise. More recently, the role of vitamin D in cardiovascular disease (CVD) prevention has been demonstrated by ourselves and others. CVD can be studied in children using established surrogate markers such as carotid-intima thickness (cIMT).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institute of Child Health/Great Ormond Street Hospital Research Ethics Committee, 2008, ref: 08 /H0713/38

Study design
Non-randomised interventional treatment trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Medicines for Children Research Network; Subtopic: All Diagnoses; Disease: All Diseases

Interventions
Baseline 1,25(OH)2D levels will be measured. The alfacalcidol dose will be adjusted so as to keep the serum 1,25(OH)2D level in the normal range (40 150 pmol/L). Levels will be checked every 4 weeks so as to ensure that the 1,25(OH)2D level remains normal.

All children who are on dialysis will undergo the following scans annually or prior to transplantation (whichever is sooner):
1. cIMT, using high-resolution ultrasound of both common carotid arteries
2. PWV, using applanation tonometry to measure aortic and brachio-radial pulse wave velocity
3. Coronary artery calcification (CAC) score, using multi-slice CT scan for ECG-gated imaging of the heart

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin D

Primary outcome(s)
Blood samples taken at 4 weeks

Key secondary outcome(s))
Scans annually or prior to transplant

Completion date
30/09/2010

Eligibility

Key inclusion criteria
1. 30 children aged 5 to 18 years, either sex
2. CKD stage 5 (estimated glomerular filtration rate [GFR] less than 15 ml/min/1.73 m^2 or on dialysis)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 years

Upper age limit
18 years

Sex
All

Key exclusion criteria
1. Smokers
2. Diabetics
3. Uncontrolled hypertension
4. Inflammatory disorders
5. Receiving anti-epileptic medications
6. Liver disease

Date of first enrolment
01/01/2009

Date of final enrolment
30/09/2010

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Great Ormond Street Hospital for Children
London
United Kingdom
WC1N 1EH

Sponsor information

Organisation
Great Ormond Street Hospital for Children (UK)

ROR
https://ror.org/03zydm450

Funder(s)

Funder type
Charity

Funder Name
Kidney Research UK (UK)

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes