

Vitamin D levels in chronic kidney disease (CKD)

Submission date 29/04/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 29/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/08/2016	Condition category Urological and Genital Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Non randomised study

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

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 measure

Blood samples taken at 4 weeks

Secondary outcome measures

Scans annually or prior to transplant

Overall study start date

01/01/2009

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 m² or on dialysis)

Participant type(s)

Patient

Age group

Child

Lower age limit

5 Years

Upper age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 30; UK Sample Size: 30

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

England

United Kingdom

Study participating centre

Great Ormond Street Hospital for Children

London

United Kingdom

WC1N 1EH

Sponsor information

Organisation

Great Ormond Street Hospital for Children (UK)

Sponsor details

30 Guilford Street

London

England

United Kingdom

WC1N 1EH

Sponsor type

Hospital/treatment centre

Website

<http://www.ich.ucl.ac.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

Other non-profit organizations

Location

United Kingdom

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