# Vitamin D levels in chronic kidney disease (CKD)

Submission date	Recruitment status	<ul><li>Prospectively registered</li></ul>
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

### Contact name

Dr Lesley Rees

### Contact details

30 Guilford Street London United Kingdom WC1N 1EH

# 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 No

Yes