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Study of vitamin D therapy to improve heart function and immune response in patients with chronic kidney disease (CKD)

Submission date 05/12/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/04/2011	**Overall study status** Completed	
Last Edited 13/12/2019	**Condition category** Circulatory System	

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

10/H0709/56

Study information

Scientific Title
Impact of vitamin D supplementation on left ventricular mass on cardiac magnetic resonance imaging and immune regulation in chronic kidney disease: a randomised placebo-controlled trial

Acronym
The 5C study

Study objectives
Native vitamin D repletion results in immune modulation and regression of left ventricular hypertrophy in vitamin D deficient non-dialysis dependent chronic kidney disease (CKD) patients.

Ethics approval required
Old ethics approval format

Ethics approval(s)
North London Research Ethics Committee (REC) 3, 02/06/2010, ref: 10/H0709/56

Study design
Randomised double-blind placebo-controlled multicentre trial

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
Left ventricular hypertrophy (LVH) in patients with non-dialysis dependent chronic kidney disease (CKD stage 3b and 4)

Interventions
Oral cholecalciferol therapy 100,000 IU at week 0, 4, 8, 12, 24 and 42 or matching placebo.

Intervention Type
Supplement

Phase
Not Applicable

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

Primary outcome measure
1. 10g improvement in left ventricular mass (LVM) with oral vitamin D therapy over 1 year
2. Difference in LVM in patients treated with vitamin D compared to controls

Measured at 52 weeks from enrolment.

Secondary outcome measures
1. Reduction in cardiac fibrosis determined by biomarkers of cardiac fibrosis in serum post vitamin D3 therapy
2. Augmentation of adaptive immune response to Hepatitis B vaccination post oral vitamin D3 supplementation
3. Immune regulation with predominantly antiinflammatory response with oral vitamin D3 therapy
4. Measured at 52 weeks from enrolment.

Overall study start date
10/01/2011

Completion date
10/03/2013

Eligibility

Key inclusion criteria
1. Patients aged 18 - 75 years with CKD stage 3b-4
2. Documented 25 hydroxy vitamin D defeciency/insufficiency with serum 25 (OH)D levels between 12.5 to 75 nmol/L
3. Left ventricular mass index (LVMI) between 80 - 160 g/m2 for females and 100 - 160 g/m2 for males
4. Patients on angiotensin converting enzyme inhibitors and/or angiotensin II receptor blockers

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

50 participants randomised 1:1 into two groups

Total final enrolment
48

Key exclusion criteria
1. Presence of diabetes mellitus (type I and II)
2. Serum calcium greater than 2.55 mmol/L
3. Anaemia (Hb less than 10.0 g/dL or taking regular erythropoiesis stimulating agents)
4. Known malignancy
5. History of congestive cardiac failure or ejection fraction less than 40% on ECHO and/or plasma NT-proBNP greater than 500 pg/ml
6. Uncontrolled hypertension (blood pressure [BP] greater than 150/90 mmHg despite anti-hypertensive medication)
7. Significant valvular heart disease identified on transthoracic ECHO
8 Conditions that may influence collagen metabolism such as recent (less than 6 months) surgery or trauma, fibrotic diseases or active inflammatory conditions
9. Immunosuppressive medications
10. Presence of arterio-venous fistula for dialysis access
11. History of previous myocardial infarction (Trop T greater than 0.5)

Date of first enrolment
10/01/2011

Date of final enrolment
10/03/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Guy's and St. Thomas' Hospital NHS Trust
London
United Kingdom
SE1 9RT

Sponsor information

Organisation
Guy's and St. Thomas' NHS Foundation Trust (UK)

Sponsor details

Research and Development Office
16th Floor
Guys Tower
Great Maze Pond
St. Thomas' Street
London
England
United Kingdom
SE1 9RT
-
karen.ignatian@gstt.nhs.uk

Sponsor type
Hospital/treatment centre

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

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Charity

Funder Name
Guy's and St Thomas' Charity (UK)

Alternative Name(s)
Guy's and St Thomas' Charity, Guy's and St Thomas' Foundation, GSTTFoundation

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Funder Name
British Heart Foundation (BHF) (UK)

Alternative Name(s)

the_bhf, The British Heart Foundation, BHF

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/03/2020

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?
Results article	results	12/12/2019	13/12/2019	Yes	No