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The impact of vitamin D supplementation in chronic heart failure

Submission date 25/06/2008	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 31/07/2008	**Overall study status** Completed	
Last Edited 22/05/2017	**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
N/A

Study information

Scientific Title
Examining the pleiotropic actions of vitamin D supplementation in patients with chronic heart failure

Study objectives
Chronic heart failure (CHF) is a condition characterised by symptoms of exercise intolerance due to shortness of breath and fatigue. Despite recent advances, patients suffer an inexorable decline in quality of life, have frequent hospital admissions, and a high yearly mortality rate. Cardinal features of CHF include heart muscle weakness (left ventricular dysfunction [LVSD]), muscle wasting and fatigue, neurohormonal activation with increased sympathetic activity, immune activation, insulin resistance, and peripheral vascular dysfunction with increased vascular resistance. In addition to its known effects on bone and mineral metabolism, vitamin D has recently been shown to be important in normal muscle function (both heart and skeletal muscle), control of immune function, insulin production and release and arterial relaxation, and low vitamin D levels are associated with high parathyroid levels which contribute to renal failure and salt imbalance. CHF patients are frequently vitamin D deficient, which might contribute to their ongoing symptoms. We want to find out if supplementing vitamin D deficient CHF patients with high-dose vitamin D for 12 months improves their heart function, quality of life, exercise tolerance, immune activation renal function and peripheral vascular function.

On 17/04/2012 the following changes were made to the trial record:
1. The anticipated end date was changed from 31/12/2012 to 01/05/2012 and the trial is in follow-up phase.
2. The sources of funding field was updated. The previous text was 'British Heart Foundation (BHF) (UK) - application in progress; National Institute for Health Research (NIHR) (UK) - Clinical Scientist Award for Applied Clinical Research: application in progress'

Ethics approval required
Old ethics approval format

Ethics approval(s)
Leeds West Research Ethics Board approval pending, date of submission 17/07/2008, ref: 08 /H1307/94

Study design
Double-blind randomised placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Chronic heart failure

Interventions
100 µg vitamin D or placebo per day for 12 months

Intervention Type
Supplement

Phase
Not Specified

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

Primary outcome measure
Left ventricular function, assessed by cardiac magnetic resonance at baseline and 12 months

Secondary outcome measures
1. Symptom status (New York Heart Association status), measured at baseline, 1, 4, 8 and 12 months
2. Exercise tolerance, measured at baseline and 12 months
3. Quality of life (Minnesota living with heart failure questionnaire, European Quality of Life instrument [EQ5D] and a 19-item Likert scale index [CASP-19]), measured at baseline, 1, 4, 8 and 12 months
4. Flow-mediated dilatation, measured at baseline and 12 months
5. Immune status, measured at baseline and 12 months
6. Insulin resistance, measured at baseline and 12 months
7. Autonomic activation, measured by heart rate variability at baseline and 12 months
8. Renal function, measured at baseline, 1, 4, 8 and 12 months
9. B-type natriuretic peptide (BNP), measured at baseline, 1, 4, 8 and 12 months

Overall study start date
01/01/2009

Completion date
01/05/2012

Eligibility

Key inclusion criteria
1. Class II and III heart failure due to left ventricular systolic dysfunction (left ventricular ejection fraction less than or equal to 40%)
2. Stable symptoms for 3 months on maximally tolerated medical therapy with no recent change

in medication
3. Able to give informed written consent
4. Aged greater than 18 years, both sexes

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Currently taking (or have taken in the previous 3 months) calcium or other vitamin supplements
2. Currently prescribed amlodipine or other calcium channel antagonists (intake of spironolactone will be recorded)
3. CHF due to untreated valvular heart disease
4. History of primary hyperparathyroidism, sarcoidosis, tuberculosis or lymphoma
5. Vitamin D levels greater than 50 nmol/l

Date of first enrolment
01/01/2009

Date of final enrolment
01/05/2012

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Leeds
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Sponsor information

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Sponsor type
University/education

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ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Other

Funder Name
Josephine Lansdell Trust via the British Medical Association (BMA) (UK)

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