ISRCTN51372896 https://doi.org/10.1186/ISRCTN51372896

Is vitamin D supplementation associated with an improvement in functional capacity in older people with vitamin D insufficiency and chronic heart failure? A double blind, placebo controlled trial.

Submission date
04/07/2005

Recruitment status
No longer recruiting

Registration date
03/08/2005

Overall study status
Completed

Last Edited
28/02/2018

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Small studies have shown that vitamin D, a hormone that the skin usually makes using sunshine, may be able to improve muscle function pressure in some people. The majority of people in Scotland have low levels of vitamin D, and we know that people with heart failure have both low vitamin D levels and weaker muscles than usual. The weakness of the muscles is one of the reasons why people with heart failure become tired and breathless easily.
The aim of the study is to find out if giving extra vitamin D to people who have heart failure helps to improve muscle function, and see if giving vitamin D can improve some other measures of heart function and inflammation that are affected by heart failure.

Who can participate?
Adults aged 70 years or over with chronic heart failure

What does the study involve?
The study lasts for 20 weeks. Participants are randomly allocated into one of two groups, and given either a capsule of vitamin D or a placebo (dummy) at the start of the study, and then again 10 weeks later.
Participants are assessed at the start, and at 10 and 20 weeks. Each visit will 1.5 hours. At each visit, participants have some or all of the following are measured, depending on which visit it is:
- Blood pressure
- Take a blood sample
- Walk up and down a corridor for six minutes to see how far they can walk
- Time you whilst you get out of a chair and walk a few paces
- Wear a small box (accelerometer) on their waistband during the day for a week. This records movement, to measure how active you are.
- Answer two questionnaires about quality of life and heart failure symptoms

What are the possible benefits and risks of participating?
Although this dose of vitamin D has been used before and is known to be safe there is a small possibility of side effects. Participants are closely monitored for side effects caused by high calcium levels: sickness, diarrhoea, thirst or dizziness. To reduce the chance of vitamin D increasing the calcium level in their blood, participants are asked not to take vitamin D supplements or calcium supplements whilst taking part in this study.
Having blood taken can cause some bruising. The blood pressure cuff causes mild discomfort to some people. Participants may feel tired after the six minute walk depending on how much walking they usually do.

Where is the study run from?
Ninewells Hospital Dundee (UK)

When is the study starting and how long is it expected to run for?
June 2004 to December 2008

Who is funding the study?
Biomedical and Therapeutics Research Committee (UK)

Who is the main contact?
Dr Miles Witham (Scientific)
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2004-002116-28

Protocol serial number
2004CV12

Study information

Scientific Title
Is Vitamin D supplementation associated with an improvement in functional capacity in older people with chronic heart failure? A double blind, placebo controlled trial

Study objectives
That oral administration of 100,000 U of ergocalciferol every 10 weeks will improve exercise capacity, daily activity and quality of life in older, frail heart failure patients

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Tayside Research Ethics Committee, 21/9/2004, ref: 04/S1401/128
2. Fife and Forth Valley Research Ethics Committee, 15/02/2008, ref: 08/S0501/13

Study design
Double blind placebo controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic Heart Failure

Interventions
100,000 Units of oral Ergocalciferol (Vitamin D2) every 10 weeks versus placebo

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Ergocalciferol

Primary outcome(s)
Current primary outcome measure (as of 28/02/2018):
Six minute walk distance measured using the six minute walk test at baseline, 10 and 20 weeks.

Previous primary outcome measure:
Six minute walk distance

Key secondary outcome(s))
Current secondary outcome measures (as of 28/02/2018):
1. Mobility is measured using the Timed Up and Go test at baseline, 10 and 20 weeks
2. Daily activity is measured by triaxial accelerometry at baseline, 10 and 20 weeks

3. Health status and Quality of life are measured using FLP and Minnesota LWHF questionnaires at baseline, 10 and 20 weeks
4. B-type natriuretic peptide (BNP), renin, aldosterone, and tumour necrosis factor (TNF) alpha are measured using ELISA assays at baseline, 10 and 20 weeks
5. Vitamin D deficiency is measured using the 25OHD test at baseline, 10 and 20 weeks

Previous secondary outcome measures:
1. Timed up and go test
2. Daily activity by triaxial accelerometry
3. Health status and Quality of life (FLP and Minnesota LWHF questionnaires)
4. B-type natriuretic peptide (BNP), renin, aldosterone, angiotensin II, tumour necrosis factor (TNF) alpha

Completion date
31/12/2008

Eligibility

Key inclusion criteria
1. Age 70 years or over
2. Vitamin D levels of 20 µg/l (50 nmol/l) or less
3. Left ventricular systolic dysfunction on echocardiography, contrast ventriculography or radionuclide ventriculography
4. Clinical diagnosis of chronic heart failure, New York Heart Association class II and III

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Key exclusion criteria
1. Mini Mental State examination score <15/30
2. Serum creatinine >200 umol/l
3. Systolic blood pressure <90 mmHg
4. Corrected calcium >2.55 mmol/l
5. Metastatic malignancy
6. Clinical diagnosis of symptomatic osteomalacia
7. Patients with a history of recurrent falls
8. Patients unable to walk without human assistance

Date of first enrolment
01/06/2005

Date of final enrolment
31/05/2008

Locations

Countries of recruitment
United Kingdom

Scotland

Study participating centre
Section of Ageing and Health
Dundee
United Kingdom
DD1 9SY

Sponsor information

Organisation
University of Dundee (UK)

ROR
https://ror.org/03h2bxq36

Funder(s)

Funder type
Government

Funder Name
Biomedical and Therapeutics Research committee, Chief Scientist Office, Scottish Executive (CZB/4/300)

Results and Publications

Individual participant data (IPD) sharing plan
Study data are available for non-commercial, bona-fide academic analyses in collaboration with the authors; decisions on data access will be made between the investigators and the Sponsor

(University of Dundee). Participant consent for unrestricted sharing of individual participant data was not obtained
Contact for data sharing: Dr Catrina Forde (c.forde@dundee.ac.uk)

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/03/2010		Yes	No
Basic results		28/02/2018	28/02/2018	No	No