

A controlled intervention study of vitamin D supplementation on neuromuscular and psychomotor function in elderly people who fall

Submission date

23/01/2004

Recruitment status

No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

18/11/2010

Condition category

Nutritional, Metabolic, Endocrine

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

King's College Hospital

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SE22 8PT

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

REC00304

Study information

Scientific Title

Study objectives

Fractures in the elderly are a major health problem with considerable costs to the NHS. Vitamin D deficiency occurs in up to 50% of housebound elderly people and is an important contributor to fractures. In addition to osteoporosis, the myopathy and neuropathy associated with Vitamin D deficiency may contribute to fractures through falls and impaired neuroprotective responses. Vitamin D supplementation can prevent peripheral fractures in older people.

We hypothesize that Vitamin D supplementation in Vitamin D deficient elderly people results in improved neuromuscular and psychomotor function.

This will be a collaborative, bidisciplinary investigation of patients aged over 65 years who have had a fall (identified through Accident and Emergency Department records) and are Vitamin D deficient.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Not Specified

Participant information sheet

Health condition(s) or problem(s) studied

Musculoskeletal injury due to nutritional deficiency

Interventions

- i. Vitamin D supplementation with IM ergocalciferol
- ii. Matched placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

Choice reaction time and aggregate functional performance time.

Secondary outcome measures

Fall rates.

Overall study start date

01/04/1999

Completion date

01/04/2001

Eligibility

Key inclusion criteria

Elderly patients over the age of 65 years who have had a fall and are Vitamin D deficient

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

Not provided at time of registration

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

01/04/1999

Date of final enrolment

01/04/2001

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
King's College Hospital
London
United Kingdom
SE22 8PT

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Sponsor details

The Department of Health
Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL
+44 (0)20 7307 2622
dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive London

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/05/2002		Yes	No