

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

<b>Submission date</b> 23/01/2004	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 23/01/2004	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/11/2010	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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## 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  
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+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?
<a href="#">Results article</a>	results	01/05/2002		Yes	No