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

Submission date	Recruitment status	[ ] Prospectively registered
23/01/2004	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
23/01/2004	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/11/2010	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Cameron Swift

Contact details
King's College Hospital
East Dulwich Grove
London
United Kingdom
SE22 8PT

Additional identifiers

Protocol serial number
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

Study type(s)
Not Specified

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(s)
Choice reaction time and aggregate functional performance time.

Key secondary outcome(s))
Fall rates.

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

Healthy volunteers allowed
No

Age group
Senior

Sex
All

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
United Kingdom

England

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)

Funder(s)

Funder type
Government

Funder Name
NHS Executive London

Results and Publications

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