

# Primary prevention of fractures in the elderly: randomised controlled trial (RCT) of an annual injection of vitamin D in the prevention of hip and other non-vertebral fractures

<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> 17/09/2010	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<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

### Protocol serial number

SEO148

# Study information

## Scientific Title

## Study objectives

Do annual intramuscular injections of 300,000 IU of vitamin D given in the autumn reduce the risk of hip and other non-vertebral fractures sustained by men and women aged 75 yrs & over in the general practice population

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved by the South West Multi-centre Research Ethics Committee (MREC/98/6/51)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Study type(s)

Prevention

## Health condition(s) or problem(s) studied

Injury, occupational diseases, poisoning: Musculoskeletal injury

## Interventions

Injection containing 300,000 IU Vitamin D or placebo injection given annually over three years

## Intervention Type

Supplement

## Phase

Not Specified

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

Vitamin D

## Primary outcome(s)

Incidence of hip fractures, non-vertebral fractures, falls

## Key secondary outcome(s))

Not provided at time of registration

## Completion date

01/03/2003

# Eligibility

## Key inclusion criteria

10,000 men and women over 75 years from a general practice population living independently in own homes or sheltered accommodation

## Participant type(s)

Patient

## Healthy volunteers allowed

No

## Age group

Senior

## Sex

All

## Key exclusion criteria

1. History of renal failure or stones
2. Hypercalcaemia
3. Active cancer
4. Medication history of oestrogen or biphosphonate within last 3 years
5. People taking daily oral vitamin supplements containing 400 IU or more of Vitamin D

## Date of first enrolment

01/09/2000

## Date of final enrolment

01/03/2003

# Locations

## Countries of recruitment

United Kingdom

England

## Study participating centre

Primary Medical Care

Southampton

United Kingdom

SO16 5ST

# Sponsor information

**Organisation**

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

**Funder(s)****Funder type**

Government

**Funder Name**

NHS Executive South East (UK)

**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?
<a href="#">Results article</a>	results	01/12/2007		Yes	No