

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

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 17/09/2010	Condition category 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

GP practice

Study type(s)

Prevention

Participant information sheet

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 measure

Incidence of hip fractures, non-vertebral fractures, falls

Secondary outcome measures

Not provided at time of registration

Overall study start date

01/09/2000

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

Age group

Senior

Sex

Both

Target number of participants

10000

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

England

United Kingdom

Study participating centre

Primary Medical Care

Southampton

United Kingdom

SO16 5ST

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 South East (UK)

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	01/12/2007		Yes	No