

Randomised trial of vitamin D and calcium for the secondary prevention of osteoporosis related fractures in the elderly

Submission date 23/10/2000	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/10/2000	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 10/01/2014	Condition category Musculoskeletal Diseases	<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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

G9706483

Study information

Scientific Title

Acronym

RECORD

Study objectives

1. Daily oral Vitamin D or Calcium, or the two in combination, given to people aged 70 or over who have recently been successfully treated for a fracture likely to be related to osteoporosis, will decrease the incidence of subsequent fractures.
2. The cost of any effective regimen will be less than those associated with the fracture prevented

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)

Hospital

Study type(s)

Prevention

Participant information sheet

Health condition(s) or problem(s) studied

Primary care

Interventions

Daily oral Vitamin D/Calcium/Vitamin D and calcium in combination/placebo

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

1. New fractures,
2. Cost per avoided new fracture
3. Quality of life gain

Secondary outcome measures

Not provided at time of registration

Overall study start date

18/11/1998

Completion date

30/04/2004

Eligibility**Key inclusion criteria**

1. Aged 70 years or over (irrespective of sex)
2. Recent first proximal femoral or other appendicular fracture sustained in a fall or clinical vertebral fracture
3. Attending fracture clinic or hospital in-patient
4. Resident in UK
5. Able to comply with protocol (eg Mini-mental Score greater than 7)
6. Gives consent

Participant type(s)

Patient

Age group

Senior

Sex

Both

Target number of participants

5250

Key exclusion criteria

1. Multiple or high energy transfer injury
2. Inability to walk prior to presenting fracture without the support of others
3. Suffering from known malignant disease
4. Contraindication to Calcium or Vitamin D
5. Current or recent treatment with more than 200iu daily of Vitamin D, Calcium, Fluoride, Diphosphonate or Calcitonin

Date of first enrolment

18/11/1998

Date of final enrolment

30/04/2004

Locations**Countries of recruitment**

Scotland

United Kingdom

Study participating centre

Health Services Research Unit

Aberdeen

United Kingdom

AB9 2ZD

Sponsor information**Organisation**

Medical Research Council (MRC) (UK)

Sponsor details

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clinical.trial@headoffice.mrc.ac.uk

Sponsor type

Research council

Website

<http://www.mrc.ac.uk>

Funder(s)**Funder type**

Research council

Funder Name

Medical Research Council (UK)

Alternative Name(s)

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

Funding Body Type

Government organisation

Funding Body Subtype

National government

Location

United Kingdom

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	07/05/2005		Yes	No
Results article	results	01/09/2007		Yes	No
Results article	results	01/09/2009		Yes	No
Results article	results	08/01/2014		Yes	No