ISRCTN51647438 https://doi.org/10.1186/ISRCTN51647438

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

Registration date
23/10/2000

Overall study status
Completed

Last Edited
10/01/2014

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Adrian Grant

Contact details
Health Services Research Unit
University of Aberdeen
Polwarth Building
Foresterhill
Aberdeen
United Kingdom
AB9 2ZD
+44 (0)1224 553908
a.grant@adn.ac.uk

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
20 Park Crescent
London
United Kingdom
W1B 1AL
+44 (0)20 7636 5422
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