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A randomised trial of nurse led clinics to promote increased use of calcium with vitamin D supplements for fracture prevention in women over 70 years

Submission date
23/01/2004

Recruitment status
No longer recruiting

Registration date
23/01/2004

Overall study status
Completed

Last Edited
01/09/2022

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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
Dr David Torgerson

Contact details
University of York
Dept of Health Studies & Centre for Health Economics
Heslington
York
United Kingdom
YO10 5DQ
+44 (0)1904 434 129
djt6@york.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
RCHA251

Study information

Scientific Title
A randomised trial of nurse led clinics to promote increased use of calcium with vitamin D supplements for fracture prevention in women over 70 years

Study objectives
To assess whether supplementation with calcium and cholecaliferol (vitamin D3) reduces the risk of fracture in women with one or more risk factors for fracture of the hip.randomised controlled trial

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethical approval for the study was obtained from the Northern and Yorkshire multicentre research ethics committee and relevant local research ethics committees.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Injury, occupational diseases, poisoning: Musculoskeletal injury

Interventions
Daily oral supplementation using 1000 mg calcium with 800 IU cholecaliferol and information leaflet on dietary calcium intake and prevention of falls, or leaflet only (control group).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
All clinical fractures

Secondary outcome measures
1. Adherence to treatment
2. Falls
3. Quality of life (measured with the 12-item short form health survey [SF-12])

Overall study start date
09/01/2001

Completion date
03/01/2004

Eligibility

Key inclusion criteria
3314 women aged 70 and over with one or more risk factors for hip fracture:
1. Any previous fracture
2. Low body weight (less than 58 kg)
3. Smoker
4. Family history of hip fracture
5. Fair or poor self reported health

Participant type(s)
Patient

Age group
Senior

Sex
Female

Target number of participants
3314

Key exclusion criteria
1. Cognitive impairment
2. A life expectancy of less than six months

Date of first enrolment
09/01/2001

Date of final enrolment
03/01/2004

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
University of York
York
United Kingdom
YO10 5DQ

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 Northern and Yorkshire (UK)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		30/04/2005		Yes	No
Results article		26/10/2005		Yes	No