

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

☐ Prospectively registered

☐ Protocol

Registration date

23/01/2004

Overall study status

Completed

☐ Statistical analysis plan

☒ Results

Last Edited

01/09/2022

Condition category

Injury, Occupational Diseases, Poisoning

☐ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

All clinical fractures

Key secondary outcome(s))

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

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Female

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**

United Kingdom

England

Study participating centre

University of York

York

United Kingdom

YO10 5DQ

Sponsor information

Organisation

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

Funder(s)

Funder type

Government

Funder Name

NHS Executive Northern and Yorkshire (UK)

Results and Publications

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