

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

Contact name

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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