

Combination therapy using calcium/vitamin D and protein/calorie supplements in nutritionally deficient women

Submission date 01/03/2001	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 01/03/2001	Overall study status Completed	☐ Protocol
Last Edited 12/01/2009	Condition category Musculoskeletal Diseases	☐ Statistical analysis plan
		☒ Results
		☐ 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
AP0714

Study information

Scientific Title

A randomised controlled trial of combination therapy using calcium/vitamin D and protein /calorie supplements in nutritionally deficient women: an assessment of changes in osteoporotic fracture risk

Study objectives

To investigate the effects of dietary advice and nutritional supplementation on bone mineral density.

Ethics approval required

Old ethics approval format

Ethics approval(s)

The Research Ethics Committee of the Guys and St Thomas Hospital NHS Trust gave approval

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoporosis

Interventions

Women meeting the entry criteria will be randomised to one of two groups:

1. A control group will receive calcium/vitamin D only
2. The second group will receive dietary advice and nutritional supplements to increase their dietary intake and calcium/vitamin D

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Body composition and bone mineral density (BMD), assessed at baseline and 12 months.

Key secondary outcome(s)

Biochemical markers of bone turnover, measured at baseline and at 1, 3, 6, 9 and 12 months.

Completion date

31/08/2001

Eligibility

Key inclusion criteria

1. Women over 70 years
2. Body mass index of less than 21 kg/m²
3. Osteoporosis at the femoral neck and/or total hip

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

Female

Key exclusion criteria

1. Evidence of any progressive wasting disease, e.g. carcinomatosis, severe malabsorption
2. Severe renal impairment (estimated glomerular filtration rate [GFR] less than or equal to 45 ml/min)
3. Severe cardiorespiratory diseases
4. Endocrine diseases, e.g., hyperparathyroidism, hyperthyroidism
5. Therapy with drugs known to interfere with bone metabolism such as steroids, vitamin D or its derivatives, bisphosphonates, oestrogen, raloxifene
6. Cognitive impairment (abbreviated mental test score 7 or below)

Date of first enrolment

01/09/1999

Date of final enrolment

31/08/2001

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre

Senior Lecturer

London

United Kingdom

SE1 7EH

Sponsor information

Organisation

Action Medical Research (UK)

ROR

<https://ror.org/01wcqa315>

Funder(s)**Funder type**

Charity

Funder Name

Action Medical Research (UK)

Alternative Name(s)

action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type

Private sector organisation

Funding Body Subtype

Trusts, charities, foundations (both public and private)

Location

United Kingdom

Results and Publications**Individual participant data (IPD) sharing plan****IPD sharing plan summary****Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2003		Yes	No