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

Submission date 01/03/2001	**Recruitment status** No longer recruiting
Registration date 01/03/2001	**Overall study status** Completed
Last Edited 12/01/2009	**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

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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

Primary study design
Interventional

Study design
Randomised controlled trial

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/m^2
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