ISRCTN62937696 https://doi.org/10.1186/ISRCTN62937696

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

Contact name
Dr Geeta Hampson

Contact details
Senior Lecturer
Department of Chemical Pathology
St Thomas' Hospital
Lambeth Palace Road
London
United Kingdom
SE1 7EH
+44 (0)20 7928 9292 ext 2881
geeta.hampson@kcl.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

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

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

Overall study start date
01/09/1999

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

Age group
Senior

Sex
Female

Target number of participants
71

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
England

United Kingdom

Study participating centre
Senior Lecturer
London
United Kingdom
SE1 7EH

Sponsor information

Organisation
Action Medical Research (UK)

Sponsor details
Vincent House
Horsham West Sussex
United Kingdom
RH12 2DP

Sponsor type
Charity

Website
http://www.action.org.uk/

ROR
https://ror.org/01wcqa315

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research (UK)

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

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	results	01/09/2003		Yes	No