

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

<b>Submission date</b> 01/03/2001	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 01/03/2001	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 12/01/2009	<b>Condition category</b> Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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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### Contact details

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## 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<sup>2</sup>
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?
<a href="#">Results article</a>	results	01/09/2003		Yes	No