

# Primary Care Prevention of Falls and Fractures in the elderly by Annual Vitamin D Supplementation

**Submission date**  
19/08/2005

**Recruitment status**  
No longer recruiting

☐ Prospectively registered

☐ Protocol

**Registration date**  
13/09/2005

**Overall study status**  
Completed

☐ Statistical analysis plan

☒ Results

**Last Edited**  
09/02/2016

**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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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

NHMRC 251682

# Study information

## Scientific Title

Primary Care Prevention of Falls and Fractures in the elderly by Annual Vitamin D Supplementation

## Acronym

Vital D Study

## Study objectives

That an annual high-dose (500,000 IU) of 25-hydroxyvitamin D will reduce the rate of fractures and falls compared to placebo in older women.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

1. Barwon Health Human Research Ethics Committee (ref: 02/60)
2. University of Melbourne Human Research Ethics Committee (HREC) (ref: 0200700)

## Study design

Randomised controlled trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Not specified

## Study type(s)

Prevention

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Fractures, osteoporosis and falls.

## Interventions

Current interventions as of 11/11/2009:  
500,000 IU cholecalciferol or placebo

Previous interventions:

500,000 IU ergocalciferol or placebo annually

## Intervention Type

Supplement

**Phase**

Not Specified

**Drug/device/biological/vaccine name(s)**

25-hydroxyvitamin D

**Primary outcome measure**

Reduction of fracture rate in active arm compared to placebo.

**Secondary outcome measures**

1. Reduction in rate of falls
2. Improvement in mental well-being
3. Duration of independent residency
4. Reduction in total healthcare utilisation (added 11/11/2009)

Substudy group are tested for various parameters of muscle strength, balance, gait and mobility.

**Overall study start date**

01/04/2003

**Completion date**

30/09/2008

## **Eligibility**

**Key inclusion criteria**

1. Female
2. Over 70 years old
3. High risk of falls or fracture

**Participant type(s)**

Patient

**Age group**

Senior

**Sex**

Female

**Target number of participants**

2300

**Key exclusion criteria**

1. Hypercalcemia
2. Bone-trophic medications
3. Renal disease

**Date of first enrolment**

01/04/2003

**Date of final enrolment**

30/09/2008

## **Locations**

**Countries of recruitment**

Australia

**Study participating centre**

Department of Clinical and Biomedical Sciences

Geelong

Australia

3220

## **Sponsor information**

**Organisation**

The University of Melbourne (Australia)

**Sponsor details**

Grattan Street

Parkville

Australia

3010

**Sponsor type**

University/education

**Website**

<http://www.unimelb.edu.au>

**ROR**

<https://ror.org/01ej9dk98>

## **Funder(s)**

**Funder type**

Research council

**Funder Name**

National Health and Medical Research Council (NHMRC) (Australia) (refs: 251682, 509109 and 509310)

**Alternative Name(s)**

NHMRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Australia

**Funder Name**

Commonwealth Department of Health and Ageing RC (Australia) (ref: 100505 8)

## 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 of recruitment strategies	25/11/2009		Yes	No
<a href="#">Results article</a>	main results	12/05/2010		Yes	No
<a href="#">Results article</a>	mental well-being results	01/05/2011		Yes	No
<a href="#">Results article</a>	results	01/07/2014		Yes	No
<a href="#">Results article</a>	results	01/03/2015		Yes	No