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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

Registration date
13/09/2005

Overall study status
Completed

Last Edited
09/02/2016

Condition category
Injury, Occupational Diseases, Poisoning

[_] 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
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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?
Results article	results of recruitment strategies	25/11/2009		Yes	No
Results article	main results	12/05/2010		Yes	No
Results article	mental well-being results	01/05/2011		Yes	No
Results article	results	01/07/2014		Yes	No
Results article	results	01/03/2015		Yes	No