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Vitamin D in older people

Submission date	Recruitment status	[X] Prospectively registered
16/08/2012	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
16/08/2012	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
29/08/2019	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Vitamin D is essential for healthy bones and muscles, particularly in older people where low levels contribute to weak bones and falls. Although vitamins generally come from the diet, in the case of vitamin D, the majority of people actually get most of it from sunlight. Almost every cell in the body contains a vitamin D receptor that is vital for a variety of functions. Low vitamin D therefore can prevent tissues from carrying out their normal functions, which can lead to a range of long-term health conditions, such as weak bones, heart disease and problems with the immune system. People over the age of 70 slowly lose bone density over time, and vitamin D may help to slow this loss down. The aim of this study is to look at the effectiveness of three doses of vitamin D supplementation to prevent bone loss, given each month for a year on the change in bone density in older adults at risk of vitamin D deficiency.

Who can participate?
Men and women aged 70 years and over who are living in the community and are able to walk.

What does the study involve?
Participants are randomly allocated to one of three groups. Each group are given vitamin D supplements to take at different doses. The supplement is in the form of oil which is taken by mouth. There are six study visits during the study, two at the start, then every three months until the last visit at one year later, where participants are given the study supplement, have a blood test taken, and provide a urine sample. Before these visits, participants are asked not to eat anything after 10pm the night before. Participants also undergo two Dexa scans, which measure done density and complete questionnaires about diet and health, quality of life and a sunshine exposure.

What are the possible benefits and risks of participating?
Not provided at time of registration.

Where is the study run from?
Newcastle University (UK)

When is the study starting and how long is it expected to run for?
March 2016 to February 2018

Who is funding the study?
Arthritis Research UK (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
2011-004890-10

Protocol serial number
12356

Study information

Scientific Title
Optimising Vitamin D Status in Older People: A Randomised Controlled Trial of Vitamin D Supplementation

Acronym
VDOP

Study objectives
This is a non-commercial single centre study to determine the efficacy of three doses of vitamin D supplementation to prevent bone loss, given each month for a year on the change in Bone Mineral Density (BMD) in subjects aged 70 years or older, at risk of vitamin D deficiency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee North East – Sunderland, 13/04/2012, ref: 12/NE/0050

Primary study design
Interventional

Study design
Randomised interventional trial

Study type(s)
Screening

Health condition(s) or problem(s) studied
Musculoskeletal diseases

Interventions
375 participants will be recruited from GP practices from the Newcastle area (within the Primary Care Research Network Northern & Yorkshire) and will be randomised into one of 3 groups as described below. Participants will be given double-blind study supplement and asked to attend the Clinical Ageing Research Unit (CARU) for a total of 6 visits.

Participants will be randomised into the following groups:
Group 1: Oral vitamin D3 – 12,000 IU once monthly which is equivalent to 10 mcg /day
Group 2: Oral vitamin D3 – 24,000 IU once monthly which is equivalent to 20 mcg /day
Group 3: Oral vitamin D3 – 48,000 IU once monthly which is equivalent to 40 mcg /day

Follow Up Length: 12 month(s); Study Entry : Single Randomisation only

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Change in BMD at the hip (total hip BMD)

Key secondary outcome(s)
Changes in achieved plasma 250HD

Completion date
06/06/2014

Eligibility

Key inclusion criteria
Inclusion criteria as of 07/04/2017:
1. Ambulant, community dwelling men and women aged 70 years and above (by end April2013)

2. Individuals capable of giving informed consent on their own behalf
3. Individuals willing to attend the Study Centre (CARU) on six occasions and to be contacted by telephone at monthly intervals between study visits over twelve months

Original inclusion criteria:
1. Ambulant, community dwelling men and women aged 70 years and above
2. Individuals capable of giving informed consent on their own behalf
3. Individuals willing to attend the Study Centre (CARU) on six occasions and to be contacted by telephone at monthly intervals between study visits over twelve months
4. Male and female participants
5. > 70 years old

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
379

Key exclusion criteria
Exclusion criteria as of 07/04/2017:
1. Current antiresorptive or anabolic treatment for osteoporosis
2. Treatment with bisphosphonates for osteoporosis in past two years
3. Current supplement use of vitamin D (>400 IU/day) or calcium (>500 mg/day) (including use of over-the-counter preparations)
4. Fragility fracture in the previous six months
5. Known primary hyperparathyroidism
6. Hypercalcaemia (albumin-adjusted plasma calcium > 2.60 mmol/l)
7. Renal impairment (Stage 4-5 Chronic Kidney Disease: eGFR < 30 ml/min/1.73m2)
8. History of renal stones

Original exclusion criteria:
1. Current antiresorptive or anabolic treatment for osteoporosis.
2. Treatment with bisphosphonates for osteoporosis in past two years.
3. Current use of vitamin D (>400 IU/day) or calcium (>500 mg/day) (including use of over-the-counter preparations).
4. Fragility fracture in the previous six months.
5. Known primary hyperparathyroisism.
6. Hypercalcaemia (albumin-adjusted plasma calcium > 2.60 mmol/l).
7. Renal impairment (Stage 4-5 Chronic Kidney Disease: GFR < 30 ml/min/1.73m2).
8. History of renal stones.
9. Peanut allergy

Date of first enrolment
08/11/2012

Date of final enrolment
06/06/2014

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Newcastle University
Newcastle Upon Tyne
United Kingdom
NE2 4HH

Sponsor information

Organisation
Newcastle Joint Research Office

ROR
https://ror.org/01kj2bm70

Funder(s)

Funder type
Charity

Funder Name
Arthritis Research UK

Alternative Name(s)

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study is not expected to be made available due to lack of consent from trial participants for sharing of trial data. A formal request may be made to the Chief Investigator and following ethical approval via a proportionate review from a UK-REC data may be shared with non-collaborators.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2019	10/01/2019	Yes	No
Protocol article	protocol	17/09/2013		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	version V3	22/08/2012	07/04/2017	No	Yes