

# Vitamin D in older people

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| <b>Submission date</b><br>16/08/2012   | <b>Recruitment status</b><br>No longer recruiting     | <input checked="" type="checkbox"/> Prospectively registered<br><input checked="" type="checkbox"/> Protocol |
| <b>Registration date</b><br>16/08/2012 | <b>Overall study status</b><br>Completed              | <input type="checkbox"/> Statistical analysis plan<br><input checked="" type="checkbox"/> Results            |
| <b>Last Edited</b><br>29/08/2019       | <b>Condition category</b><br>Musculoskeletal Diseases | <input type="checkbox"/> Individual participant data   |

## 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 bone 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?  
Dr Alexander von Wilamowitz-Moellendorff  
alexander.von-wilamowitz-moellendorff@newcastle.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Alexander von Wilamowitz-Moellendorff

**Contact details**  
Newcastle Clinical Trials Unit  
Newcastle University  
1-4 Claremont Terrace  
Newcastle Upon Tyne  
United Kingdom  
NE2 4AE  
+44 191 208 2524  
alexander.von-wilamowitz-moellendorff@newcastle.ac.uk

## 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

**Study design**

Randomised interventional trial

**Primary study design**

Interventional

**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 25OHD

**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/1.73m<sup>2</sup>)
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 hyperparathyroidism.
6. Hypercalcaemia (albumin-adjusted plasma calcium > 2.60 mmol/l).
7. Renal impairment (Stage 4-5 Chronic Kidney Disease: GFR < 30 ml/min/1.73m<sup>2</sup>).
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? |
|---|------------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>               | results    | 01/01/2019   | 10/01/2019 | Yes            | No              |
| <a href="#">Protocol article</a>              | protocol   | 17/09/2013   |            | Yes            | No              |
| <a href="#">HRA research summary</a>          |            |              | 28/06/2023 | No             | No              |
| <a href="#">Participant information sheet</a> | version V3 | 22/08/2012   | 07/04/2017 | No             | Yes             |