

Vitamin D in older people

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

EudraCT/CTIS number
2011-004890-10

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Screening

Participant information sheet

See additional files

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 measure

Change in BMD at the hip (total hip BMD)

Secondary outcome measures

Changes in achieved plasma 250HD

Overall study start date

01/10/2012

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 April 2013)
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

Age group

Adult

Sex

Both

Target number of participants

UK Sample Size: 375

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 hyperparathyroidism.
6. Hypercalcaemia (albumin-adjusted plasma calcium > 2.60 mmol/l).
7. Renal impairment (Stage 4-5 Chronic Kidney Disease: GFR < 30 ml/min/1.73m²).
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

England

United Kingdom

Study participating centre

Newcastle University

Newcastle Upon Tyne

United Kingdom

NE2 4HH

Sponsor information

Organisation

Newcastle Joint Research Office

Sponsor details

Level 1 Regent Point

Regent Farm Road

Gosforth

Newcastle Upon Tyne

England

United Kingdom
NE1 4LP
+44 191 282 4518
Trust.R&D@nuth.nhs.uk

Sponsor type

Hospital/treatment centre

Website

<http://www.newcastle-hospitals.org.uk/>

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

Publication and dissemination plan

The study results will be published in peer reviewed journals and presented at scientific conferences. A lay summary of the main findings will be circulated to all trial participants.

Intention to publish date

31/12/2018

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?
Protocol article	protocol	17/09/2013		Yes	No
Participant information sheet	version V3	22/08/2012	07/04/2017	No	Yes
Results article	results	01/01/2019	10/01/2019	Yes	No
HRA research summary			28/06/2023	No	No