

# Trial of vitamin D supplementation in chronic obstructive pulmonary disease (COPD)

<b>Submission date</b> 12/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 12/05/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 03/02/2016	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English Summary

### Background and study aims

Vitamin D - the sunshine vitamin - is best known for its effects on bone health. Profound deficiency causes rickets, a condition that causes the bones on children to become soft and weak, which, in turn, can lead to bone deformities. More moderate deficiency, commonly seen in the UK during winter and spring, can make people more susceptible to respiratory infections. Respiratory infections cause 20% of GP consultations, 300,000 hospital admissions and 30,000 deaths per year. Patients with chronic obstructive pulmonary disease (COPD) are at high risk of such infections. Studies have shown that vitamin D 'switches on' the production of natural antibiotic substances that can kill viruses and bacteria in cells that fight infection. One small study, originally designed to look at the effects of vitamin D on bone health has shown that patients receiving high-dose vitamin D were 3 times less likely to have cold and 'flu symptoms than those who received placebo (dummy pill). The primary aim of the study is to determine whether vitamin D supplementation is a cost-effective and acceptable way to reduce acute respiratory illness in patients with COPD.

### Who can participate?

Patients aged 40 years and over and diagnosed with COPD

### What does the study involve?

Participants are randomly allocated to one of two groups. Those in group 1 are given Vigantol (a form of vitamin D). Those in group 2 are given a placebo. All participants attend five study visits over the course of a year and are also contacted by telephone on five occasions at intervals between scheduled visits. Participants are asked to complete a daily diary of chest symptoms, give blood samples and perform breathing and muscle strength tests at the beginning, the middle and the end of the study.

### What are the possible benefits and risks of participating?

Not provided at time of registration

### Where is the study run from?

A number of GP surgeries in London and Norfolk.

When is the study starting and how long is it expected to run for?  
September 2009 to August 2013

Who is funding the study?  
National Institute for Health Research (UK)

Who is the main contact?  
Ms Wai Yee James

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Ms Wai Yee James

**Contact details**  
Centre for Health Sciences  
2 Newark Street  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**  
NCT00977873

**Secondary identifying numbers**  
7831

## Study information

**Scientific Title**  
Randomised, multicentre, double-blind, placebo-controlled trial of vitamin D supplementation in patients with chronic obstructive pulmonary disease (COPD)

**Study hypothesis**  
The primary aim of the study is to determine whether vitamin D supplementation is a cost-effective and acceptable strategy to reduce acute respiratory illness in patients with COPD.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**

**Study design**

Multicentre randomised interventional prevention trial

**Primary study design**

Interventional

**Secondary study design**

Randomised controlled trial

**Study setting(s)**

GP practice

**Study type(s)**

Prevention

**Participant information sheet**

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

**Condition**

Topic: Inflammatory and Immune System; Subtopic: Inflammatory and Immune System (all Subtopics); Disease: Immunology and inflammation

**Interventions**

Vigantol, 3 mg or miglyol oil (placebo), to be administered every two months over a twelve months period, in total of six doses. Patients will be followed up at these post-dose time points: 2 months, 6 months and 12 months.

**Intervention Type**

Supplement

**Phase**

Not Applicable

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

Vitamin D

**Primary outcome measure**

Time from randomisation to first moderate or severe COPD exacerbation

**Secondary outcome measures**

Respiratory morbidity. Measured at screen visit, randomisation visit, 2 months post-dose, 6 months post-dose and 12 months post-dose.

**Overall study start date**

11/09/2009

**Overall study end date**

## Eligibility

### Participant inclusion criteria

1. Medical record diagnosis of COPD, emphysema or bronchitis
2. Post-bronchodilator forced expiratory volume in one second (FEV1)/forced vital capacity (FVC) less than 70% or post-bronchodilator FEV1/slow vital capacity (VC) less than 70%
3. Post-bronchodilator FEV1 less than 80% predicted
4. Age 40 years on day of first dose of IMP, either sex
5. Smoking history 15 pack-years
6. Exacerbation of COPD requiring treatment with antibiotics and/or systemic corticosteroids within 12 months of screening visit
7. Contactable by telephone and able to attend face-to-face review at 2, 6 and 12 months post-enrolment
8. If a woman of child-bearing potential, is sexually abstinent or has negative pregnancy test within 7 days of recruitment and agrees to use reliable form of contraception until she has completed the study
9. Able to give written informed consent to participate

### Participant type(s)

Patient

### Age group

Adult

### Sex

Both

### Target number of participants

Planned sample size: 240

### Participant exclusion criteria

1. Current diagnosis of asthma
2. Known clinically significant bronchiectasis
3. Known sarcoidosis, hyperparathyroidism, nephrolithiasis, active tuberculosis, vitamin D intolerance, liver failure, renal failure, terminal illness, lymphoma or other malignancy not in remission for 3 years
4. Any other condition that, in an investigator's judgement, might compromise patient safety or compliance, interfere with evaluation or preclude completion of the study
5. COPD requiring long-term oxygen therapy 12 hours per day
6. Taking benzothiadiazine derivative, cardiac glycoside, carbamazepine, phenobarbital, phenytoin or primidone
7. Taking dietary supplement containing vitamin D up to 2 months before first dose of IMP
8. Treatment with any investigational medical product or device up to 4 months before first dose of IMP
9. Breastfeeding, pregnant or planning a pregnancy
10. Baseline corrected serum calcium greater than 2.65 mmol/L
11. Baseline serum creatinine greater than 125 micromol/L
12. Upper respiratory tract infection (URTI) or COPD exacerbation up to 28 days before first dose of IMP

- 13. Inability to use spirometer
- 14. Inability to complete symptom diary

**Recruitment start date**

11/09/2009

**Recruitment end date**

30/08/2013

## Locations

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

Centre for Health Sciences

London

United Kingdom

E1 2AT

## Sponsor information

**Organisation**

Barts and The London School of Medicine and Dentistry

**Sponsor details**

Blizard Institute of Cell and Molecular Science (ICMS)

The Blizard Building

4 Newark Street

London

England

United Kingdom

E1 2AT

**Sponsor type**

University/education

**Website**

<http://www.icms.qmul.ac.uk/>

**ROR**

<https://ror.org/00b31g692>

# Funder(s)

## Funder type

Government

## Funder Name

National Institute for Health Research

## Alternative Name(s)

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

## Funding Body Type

Government organisation

## Funding Body Subtype

National government

## Location

United Kingdom

# 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	01/12/2014		Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No