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

Submission date 12/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 12/05/2010	**Overall study status** Completed	[_] Statistical analysis plan [X] Results
Last Edited 03/02/2016	**Condition category** Respiratory	[_] Individual participant data

Plain English summary of protocol

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 no 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
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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00977873

Protocol serial number
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 objectives
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)
East London and the City Research Ethics Committees, 24/07/2009, ref: 09/H0703/76

Primary study design

Interventional

Study design
Multicentre randomised interventional prevention trial

Study type(s)
Prevention

Health condition(s) or problem(s) studied
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(s)
Time from randomisation to first moderate or severe COPD exacerbation

Key secondary outcome(s)
Respiratory morbidity. Measured at screen visit, randomisation visit, 2 months post-dose, 6 months post-dose and 12 months post-dose.

Completion date
30/08/2013

Eligibility

Key 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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key 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

Date of first enrolment
11/09/2009

Date of final enrolment
30/08/2013

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Centre for Health Sciences
London
United Kingdom
E1 2AT

Sponsor information

Organisation
Barts and The London School of Medicine and Dentistry

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

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	01/12/2014		Yes	No
HRA research summary			28/06/2023	No	No