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Randomised, multi-centre, double-blind, placebo-controlled trial of vitamin D supplementation in adult and adolescent patients with asthma

Submission date 19/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 19/05/2010	**Overall study status** Completed	
Last Edited 14/11/2022	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

ClinicalTrials.gov (NCT)
NCT00978315

Protocol serial number
7530

Study information

Scientific Title
Randomised, multi-centre, double-blind, placebo-controlled prevention trial of vitamin D supplementation in adult and adolescent patients with asthma

Acronym
Trial of vitamin D supplementation in asthma

Study objectives
Asthma is a common chronic inflammatory condition of the airways. Exacerbations of asthma cause significant morbidity and health care use in the UK. They are commonly precipitated by upper respiratory tract infections (URTI). Vitamin D deficiency is also very common in the UK. A growing body of evidence from laboratory and clinical studies suggests that vitamin D supplementation may prevent exacerbations of asthma by enhancing both anti-inflammatory and antimicrobial immune responses. The study null hypothesis is that vitamin D supplementation will not influence time to upper respiratory tract infection or time to severe asthma exacerbation in adult and adolescent patients with asthma.

Ethics approval required
Old ethics approval format

Ethics approval(s)
MREC approved (ref: 09/H0703/67)

Study design
Multicentre randomised interventional prevention trial

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Topic: Respiratory; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

Interventions
1. Dietary Supplement: Cholecalciferol + miglyol oil
2. Dietary Supplement: Miglyol oil

Intervention Type
Supplement

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Vitamin D

Primary outcome(s)
Time to first upper respiratory tract infection at one year

Key secondary outcome(s))
1. Asthma Control Test Score, measured at one year
2. Time to first severe asthma exacerbation, measured at one year
3. Proportion of participants experiencing hypercalcaemia, measured at one year
4. Time to unscheduled health service use for upper respiratory tract infection or severe asthma exacerbation, measured at one year

Completion date
30/08/2013

Eligibility

Key inclusion criteria
1. Medical record diagnosis of asthma, treated at British Thoracic Society (BTS) step 2 or above for at least 28 days before first dose of investigational medical product (IMP)
2. One or more of the following, documented within the last 3 years:
2.1. 12% increase in forced expiratory volume in one second (FEV1) after inhalation of 400 micrograms of salbutamol
2.2. 20% diurnal variability in peak expiratory flow
2.3. Methacholine PC20 (concentration of methacholine causing a 20% fall in FEV1) less than 8 g /L
3. Age 12 years and 80 years on day of first dose of IMP, either sex
4. Contactable by telephone and able to attend face-to-face review at 2, 6 and 12 months post-enrolment
5. 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
6. Able to give written informed consent to participate in the study if aged 16 years; if aged less than 16 years, able to give assent, with a parent or guardian able to give written informed consent for the subject to participate in the study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
All

Sex
All

Total final enrolment
250

Key exclusion criteria

1. Diagnosis of COPD as defined by the GOLD guidelines
2. 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
3. Any other condition that, in an investigator's judgement, might compromise patient safety or compliance, interfere with evaluation or preclude completion of the study
4. Taking benzothiadiazine derivative, cardiac glycoside, carbamazepine, phenobarbital, phenytoin or primidone
5. Taking dietary supplement containing vitamin D up to 2 months before first dose of IMP
6. Treatment with any investigational medical product or device up to 4 months before first dose of IMP
7. Breastfeeding, pregnant or planning a pregnancy
8. Baseline corrected serum calcium greater than 2.65 mmol/L
9. Baseline serum creatinine greater than 125 micromol/L
10. Smoking history greater than 15 pack-years
11. Severe asthma exacerbation or URTI up to 28 days before first dose of IMP
12. Inability to use spirometer or peak expiratory flow rate (PEFR) meter
13. Inability to complete diary of symptoms and PEFR

Date of first enrolment
01/06/2009

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 NHS Trust (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

Individual participant data (IPD) sharing plan
Not provided at time of registration

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		01/05/2015		Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes