

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

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|--|---|---|
| Submission date 19/05/2010 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 19/05/2010 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 14/11/2022 | Condition category Respiratory | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number
NCT00978315

Secondary identifying numbers

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

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 contact details to request a participant information sheet

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 measure

Time to first upper respiratory tract infection at one year

Secondary outcome measures

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

Overall study start date

01/06/2009

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

Age group

All

Sex

Both

Target number of participants

Planned sample size: 250

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**

England

United Kingdom

Study participating centre

Centre for Health Sciences

London

United Kingdom

E1 2AT

Sponsor information

Organisation

Barts and The London NHS Trust (UK)

Sponsor details

Queen Mary's Innovation Centre

5 Walden Street

London

England

United Kingdom

E1 2EF

Sponsor type

Hospital/treatment centre

Website

<http://www.bartsandthelondon.nhs.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**

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 |