# The effects of prenatal vitamin D supplementation on child health

Submission date	Recruitment status No longer recruiting	Prospectively registered		
24/06/2010		☐ Protocol		
Registration date 24/06/2010	Overall study status Completed	Statistical analysis plan		
		[X] Results		
<b>Last Edited</b> 11/07/2016	Condition category Respiratory	[] Individual participant data		
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## Plain English summary of protocol

Not provided at time of registration

## Contact information

## Type(s)

Scientific

#### Contact name

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#### Contact details

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## Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

ClinicalTrials.gov number

Secondary identifying numbers

8325

# Study information

#### Scientific Title

Effects of prenatal vitamin D supplementation on respiratory and allergic phenotypes and bone density in the first three years of life

## **Study objectives**

Asthma is the commonest chronic disease of childhood in the United Kingdom. In a recent study the prevalence of asthma in the UK was 20.9% in children aged 6 - 7 years, and 24.7% in young people aged 13 - 14 years old. Asthma is not curable once it has developed, and in most cases has its origins in early childhood. There is a justified focus on understanding the early life origins of asthma, with a view to developing primary prevention strategies.

This is a follow up study of a previously conducted randomised controlled trial (entitled 'Vitamin D deficiency and supplementation during pregnancy'). In that study, 180 mothers attending antenatal clinic at St Marys hospital were randomised at 27 weeks gestation to either no vitamin D (n = 60), 800 IU of vitamin D daily for the remainder of pregnancy (n = 60) or a single oral dose of 200,000 IU vitamin D at 27 weeks gestation.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

St Marys Hospital REC, 11/03/2010, ref: 10/H0712/13

#### Study design

Single-centre randomised interventional prevention trial

## Primary study design

Interventional

## Secondary study design

Randomised controlled trial

## Study setting(s)

Hospital

## Study type(s)

Prevention

#### Participant information sheet

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

## Health condition(s) or problem(s) studied

Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Paediatrics

#### **Interventions**

- 1. Control group: women received no vitamin D supplementation (n = 60)
- 2. Daily Vitamin D: women received 800 IU of vitamin D (ergocalciferol) daily from 27 weeks gestation until delivery (n = 60)
- 3. Stat Vitamin D: women received a single stat dose of 200,000 IU vitamin D (calciferol) at 27 weeks gestation (n = 60)

Study entry: single randomisation only

#### Intervention Type

Supplement

#### Phase

Not Applicable

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

Vitamin D supplementation

#### Primary outcome measure

Percentage (%) of children with any wheezing episode in the first 3 years of life, measured at 36 - 48 months

#### Secondary outcome measures

All measured at 36 - 48 months:

- 1. % of children using inhaled bronchodilators in the last 12 months
- 2. % of children with doctor diagnosed rhinitis
- 3. % of children with any wheezing episode in the preceding 12 months
- 4. % of children with doctor diagnosed asthma
- 5. % of children with doctor diagnosed eczema
- 6. % of children with doctor diagnosed food allergy
- 7. % of children with positive skin prick test responses
- 8. 25-hydroxyvitamin D levels
- 9. Bronchodilator responsiveness
- 10. Exhaled nitric oxide level (in parts per billion)
- 11. Nasal secretions for inflammatory mediators
- 12. Pulmonary airflow resistance and reactance at a range of frequencies using impulse oscillometry
- 13. Total number of all wheezing episodes since birth
- 14. Total number of upper and lower respiratory tract infections since birth

#### Overall study start date

01/03/2010

#### Completion date

31/05/2011

## Eligibility

Key inclusion criteria

All of the offspring of the 180 mothers recruited in the Vitamin D deficiency and supplementation during pregnancy trial are eligible and are invited to participate in this follow up study when their children are 3 years of age.

## Participant type(s)

**Patient** 

#### Age group

Child

#### Lower age limit

3 Years

#### Sex

Both

## Target number of participants

Planned sample size: 180; UK sample size: 180

#### Key exclusion criteria

Severe congenital or developmental abnormalities likely to significantly affect respiratory health or lung function, e.g., congenital thoracic dystrophy.

#### Date of first enrolment

01/03/2010

#### Date of final enrolment

31/05/2011

## Locations

#### Countries of recruitment

England

**United Kingdom** 

## Study participating centre Wright-Fleming Institute London United Kingdom W2 1PG

# **Sponsor information**

#### Organisation

Imperial College London (UK)

#### Sponsor details

South Kensington Campus (Main Campus) Imperial College London England United Kingdom SW7 2AZ

#### Sponsor type

University/education

#### Website

http://www3.imperial.ac.uk/

#### **ROR**

https://ror.org/041kmwe10

# Funder(s)

## Funder type

Charity

#### **Funder Name**

Asthma UK (UK)

#### Alternative Name(s)

Asthma UK, Asthma + Lung UK

#### **Funding Body Type**

Private sector organisation

#### **Funding Body Subtype**

Other non-profit organizations

#### 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?
Results article	results	24/06/2013		Yes	No
Results article	results	23/12/2015		Yes	No