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The effects of prenatal vitamin D supplementation on child health

Submission date	Recruitment status	[_] Prospectively registered
24/06/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
24/06/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
11/07/2016	Respiratory	

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

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