

The effects of prenatal vitamin D supplementation on child health

Submission date 24/06/2010	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 24/06/2010	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 11/07/2016	Condition category Respiratory	☐ 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

Protocol serial number
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

Primary study design

Interventional

Study design

Single-centre randomised interventional prevention trial

Study type(s)

Prevention

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Child

Lower age limit

3 Years

Sex

All

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

United Kingdom

England

Study participating centre

Wright-Fleming Institute

London

United Kingdom

W2 1PG

Sponsor information

Organisation

Imperial College London (UK)

ROR

<https://ror.org/041kmwe10>

Funder(s)

Funder type

Charity

Funder Name

Asthma UK (UK)

Alternative Name(s)

asthmalunguk, Asthma + Lung UK, Asthma UK

Funding Body Type

Private sector organisation

Funding Body Subtype

Research institutes and centers

Location

United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

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