

Primary prevention of asthma and atopy during childhood and adolescence by allergen avoidance

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 13/08/2012	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
4476

Study information

Scientific Title

Primary prevention of asthma and atopy during childhood and adolescence by allergen avoidance in infancy: a randomised controlled study

Study objectives

Asthma and allergic diseases affect millions of people in the UK. Asthma is the most common chronic disease in children. Their quality of life is severely affected, some live in a constant fear of another attack. We can significantly improve the health of future generations, if we can prevent the development of these diseases. It is therefore important to devise effective preventive strategies. It is well known that both genetic and environmental factors contribute to the development of asthma and allergy. Thus, children with a family history of allergy are at higher risk. Exposure to allergens in early childhood may be one of the most important environmental factors.

In 1990 we embarked on a study to test the effectiveness of strict dietary avoidance of food allergens combined with reduced exposure to house dust-mite allergen. Infants, at higher risk due to family predisposition, were recruited before birth and assigned randomly to prophylactic (n = 58) or control (n = 62) groups. Prophylactic group infants were either breast-fed with mothers on a low allergen diet or given hypoallergenic milk formula and exposure to house dust-mite was reduced. All 120 children have been seen at ages 1, 2, 4 and 8 years. The prophylactic children were less sensitised to allergens and developed less asthma and eczema up to the age of 8 years and there was no loss of preventive effect up to this age.

Since this study commenced in 1990, no other intervention has succeeded in achieving such an impact on asthma and allergy. These children are now 18 years. We wish to see them again and make a comprehensive assessment of their asthma and allergy status to ascertain if the effect of reduced allergen exposure in infancy continues into adolescence and early adulthood.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Portsmouth and SE Hampshire approved on the 15th February 2008 (ref: 07/H0504/188)

Study design

Single centre randomised interventional prevention trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Topic: Respiratory, Inflammatory and Immune System; Subtopic: Inflammatory and Immune System (all Subtopics), Respiratory (all Subtopics); Disease: Multiple complications, Immunology and inflammation, Respiratory

Interventions

Initially, participants in 1990 were infants at higher risk due to family predisposition. These infants were recruited before birth and assigned randomly to prophylactic (n = 58) or control (n

= 62) groups. Prophylactic group infants were either breast-fed with mothers on a low allergen diet or given hypoallergenic milk formula and exposure to house dust-mite was reduced. Follow-up was at ages 1, 2, 4 and 8 years.

In this follow-up study, a comprehensive assessment of the initial participants' (now aged 18 years) asthma and allergy status is performed to ascertain if the effect of reduced allergen exposure in infancy continues into adolescence and early adulthood.

Follow up length: 36 months

Study entry: registration with blood and saliva sample collection

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

Asthma, measured using questionnaires and assessment of other characteristics such as lung function.

Key secondary outcome(s)

1. Atopy, measured using skin prick test
2. Eczema, measured using questionnaires and SCORAD
3. Food allergy

Completion date

30/04/2010

Eligibility

Key inclusion criteria

1. Participation in the 1990 Isle of Wight Prevention Cohort Study
2. Aged 18 years or older, either sex

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

01/05/2008

Date of final enrolment

30/04/2010

Locations**Countries of recruitment**

United Kingdom

England

Study participating centre**Surgery Unit**

Southampton

United Kingdom

SO16 6YD

Sponsor information**Organisation**

Isle of Wight Healthcare NHS Trust (UK)

ROR

<https://ror.org/013aa1717>

Funder(s)**Funder type**

Government

Funder Name

National Institute for Health Research (NIHR) (UK)

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**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	01/12/2012		Yes	No