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

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
13/08/2012	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
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

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: 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 measure
Asthma, measured using questionnaires and assessment of other charateristics such as lung function.

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

Overall study start date
01/05/2008

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned sample size: 120; UK sample size: 120

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
England

United Kingdom

Study participating centre
Surgery Unit
Southampton
United Kingdom
SO16 6YD

Sponsor information

Organisation
Isle of Wight Healthcare NHS Trust (UK)

Sponsor details
St. Marys Hospital
Parkhurst Road

Newport
England
United Kingdom
PO30 5TG

Sponsor type
Hospital/treatment centre

Website
http://www.iow.nhs.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

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	01/12/2012		Yes	No