

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

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<b>Registration date</b> 24/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/08/2012	<b>Condition category</b> Respiratory	<input type="checkbox"/> 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

**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 characteristics 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?
<a href="#">Results article</a>	results	01/12/2012		Yes	No