

Allergen avoidance in infancy and development of asthma and allergy during childhood: a randomised controlled trial. Follow-up at the age of 8 yrs

Submission date 23/01/2004	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 08/02/2010	Condition category Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<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

Protocol serial number
SPGS788

Study information

Scientific Title

Study objectives

In infants genetically predisposed to atopy, allergen exposure in infancy plays a critical role in the development of phenotypic manifestations. Allergen avoidance in this period leads to a reduction in the prevalence of asthma, other allergic disorders and/or skin sensitisation.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added 08/02/10: The Isle of Wight Local Research Ethics Committee approved on the 23rd of December 1997 (ref: 35/97)

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Asthma

Interventions

Reduced allergen exposure (food and aero-allergen) in prophylactic group

Intervention Type

Other

Phase

Not Applicable

Primary outcome(s)

1. Two questionnaires to assess symptoms suggestive of allergic diseases
2. Physical examination
3. Skin prick tests
4. Pulmonary function tests and bronchial challenges
5. Total serum IgE
6. Aero-allergen screen

Key secondary outcome(s)

None

Completion date

01/05/2000

Eligibility

Key inclusion criteria

120 infants with high risk of atopy recruited antenatally, now aged 8 yrs

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Child

Lower age limit

8 years

Upper age limit

8 years

Sex

All

Key exclusion criteria

Does not match inclusion criteria

Date of first enrolment

01/05/1998

Date of final enrolment

01/05/2000

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Asthma and Allergy Research Centre

Newport

United Kingdom

PO30 5TG

Sponsor information

Organisation

NHS R&D Regional Programme Register - Department of Health (UK)

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (UK)

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	01/06/2003		Yes	No
Results article	results	01/02/2007		Yes	No