ISRCTN64243404 https://doi.org/10.1186/ISRCTN64243404

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	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 23/01/2004	**Overall study status** Completed	
Last Edited 08/02/2010	**Condition category** Respiratory	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr S H Arshad

Contact details
Asthma and Allergy Research Centre
St Mary's Hospital
Isle of Wight
Newport
United Kingdom
PO30 5TG
+44 (0)1983 822928
sha@soton.ac.uk

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)

Primary study design
Interventional

Study design
Randomised controlled trial

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