

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 <input type="checkbox"/> Protocol
Registration date 23/01/2004	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 08/02/2010	Condition category Respiratory	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Other

Study type(s)

Prevention

Participant information sheet

Not available in web format, please use contact details below to request a patient information sheet.

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 measure

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

Secondary outcome measures

None

Overall study start date

01/05/1998

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

Age group

Child

Lower age limit

8 Years

Upper age limit

8 Years

Sex

Both

Target number of participants

120

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

England

United Kingdom

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)

Sponsor details

The Department of Health

Richmond House

79 Whitehall

London

United Kingdom

SW1A 2NL

+44 (0)20 7307 2622

dhmail@doh.gsi.org.uk

Sponsor type

Government

Website

<http://www.doh.gov.uk>

Funder(s)

Funder type

Government

Funder Name

NHS Executive South East (UK)

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