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Effect of allergen avoidance in infancy on airway inflammation

Submission date	Recruitment status	[_] Prospectively registered
12/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/09/2013	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
7489

Study information

Scientific Title
Primary prevention of asthma and atopy by allergen avoidance. Do preventative measures influence the type and degree of airway inflammation?

Study objectives
Primary prevention of asthma and atopy by allergen avoidance. Do preventative measures influence the type and degree of airway inflammation?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Southampton & South West Hampshire Research Ethics Committee (B) approved on the 26th November 2008 (ref: 08/H0504/184)

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; Subtopic: Respiratory (all Subtopics); Disease: Respiratory

Interventions
Dietary and house dust mite allergy prevention.

Sputum Induction:
This involves breathing in a mist of saline solution, which helps make phlegm in the lungs, which is then collected in a sputum pot.

Exhaled Nitric Oxide reading:
Levels will be measured using the single expiratory breath method using ATS/ERS guidelines. A bio-feedback device will be used to maintain the expiratory flow rate at 50 ml/s, subjects will exhale against a resistance to prevent upper airway contamination.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Number of sputum eosinophils in the intervention versus control group.

Sputum samples will be collected during a visit to the research centre, with preparation and analysis taking place after.

Secondary outcome measures
1. Number of other cells (1) neutrophils, (2): epithelial cells in sputum in the two groups
2. Eosinophilic inflammatory markers (eosinophilic cationic protein and interleukin 5) in sputum supernatant in the two groups

Sputum samples will be collected during a visit to the research centre, with preparation and analysis taking place after.

Overall study start date
01/03/2009

Completion date
01/02/2010

Eligibility

Key inclusion criteria
Everyone (120 subjects) who participated in the original Isle of Wight Primary Prevention study will be asked if they wish to participate.

Participant type(s)
Patient

Age group
Other

Sex
Both

Target number of participants
Planned sample size: 120

Key exclusion criteria
1. Any patient who does not wish to participate
2. Any patient where their lung function test suggests that they would be at risk of significant bronchospasm and/or clinical suspicion is high that they would not tolerate sputum induction

Date of first enrolment

01/03/2009

Date of final enrolment
01/02/2010

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St Mary's Hospital IOW
Newport
United Kingdom
PO30 5TG

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) - Research for Patient Benefit (RfPB) Programme

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