

Effect of allergen avoidance in infancy on airway inflammation

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 17/09/2013	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
Mr Stephen Potter

Contact details
St Mary's Hospital IOW
David Hide Asthma and Allergy Research Centre
St. Marys Hospital
Parkhurst Road
Newport
United Kingdom
PO30 5TG

Additional identifiers

Protocol serial number
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

Intentional

Study type(s)

Prevention

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(s)

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.

Key secondary outcome(s)

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.

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

Healthy volunteers allowed

No

Age group

Other

Sex

All

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

United Kingdom

England

Study participating centre

St Mary's Hospital IOW

Newport

United Kingdom

PO30 5TG

Sponsor information

Organisation

Isle of Wight Healthcare NHS Trust (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

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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes