

The effect of Der p 1 inhalation on bronchial responsiveness to inhaled cat allergen in asthmatics sensitised to cat but not to house dust mite

Submission date 12/09/2003	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 12/09/2003	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 11/10/2016	Condition category Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

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

N0226111705

Study information

Scientific Title

The effect of Der p 1 inhalation on bronchial responsiveness to inhaled cat allergen in asthmatics sensitised to cat but not to house dust mite

Study objectives

To detect whether bronchial responsiveness to cat allergen, in a subject sensitised to cat, but not dust mite, may be enhanced by the presence of Dermatophagoides pteronyssinus 1 (Der p 1), a cysteine peptidase allergen.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Double-blind placebo-controlled randomised cross-over study

Primary study design

Interventional

Secondary study design

Randomised cross over trial

Study setting(s)

Not specified

Study type(s)

Other

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied

Asthma

Interventions

Double-blind, placebo-controlled, randomised, cross-over study. Patients are randomised to:

1. Dermatophagoides pteronyssinus 1 (Der p 1), a cysteine peptidase allergen
2. Placebo

Intervention Type

Other

Primary outcome measure

The measure of cat allergen PD20, that is the cumulative dose of cat allergen required to cause a 20% fall in forced expiratory volume in one second (FEV1).

Secondary outcome measures

Not provided at time of registration

Overall study start date

27/05/2002

Completion date

31/12/2003

Eligibility

Key inclusion criteria

10 subjects, volunteers selected from the MEU database who have had previous skin prick testing and identified as being sensitised to cat and not house dust mite

Participant type(s)

Healthy volunteer

Age group

Adult

Sex

Both

Target number of participants

10

Key exclusion criteria

Not provided at time of registration

Date of first enrolment

27/05/2002

Date of final enrolment

31/12/2003

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
North West Lung Centre
Manchester
United Kingdom
M23 9LT

Sponsor information

Organisation

Department of Health (UK)

Sponsor details

Richmond House
79 Whitehall
London
United Kingdom
SW1A 2NL

Sponsor type

Government

Website

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

Funder(s)

Funder type

Charity

Funder Name

North West Lung Centre Charity (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