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Effect of HEPA filter air cleaners (IQAir® /Incleen®) in homes of asthmatic children and adolescents sensitised to cat and dog allergens

Submission date 15/08/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 12/09/2007	**Overall study status** Completed	
Last Edited 12/04/2021	**Condition category** 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

Study information

Scientific Title
Effect of HEPA filter air cleaners (IQAir®/Incleen®) in homes of asthmatic children and adolescents sensitised to cat and dog allergens

Acronym
HEPA

Study objectives
The reduction of pet allergens in households of pet-sensitive asthmatic children with Hepa air filters reduces bronchial hyper-responsiveness after cold air challenge and possibly also pet allergen exposure after 6 and 12 months of treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Ethics Committee of the Charite in May 1999.

Study design
Randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Allergy and asthma

Interventions
Recruitment took place 3 - 4 months before the treatment started. After randomisation patients were allocated to two groups: active and sham filters placed in the living and bedroom of families with a cat or dog sensitive asthmatic child.

Filters were placed in the homes on month 0 and changed after 6 months. Treatment period was 12 months. There was no follow up after the treatment. Dust samples of house dust were collected before the treatment started (inclusion criterion pet allergen exposure greater than

500 ng/g) and on month 0, 6 and 12. They were analysed for Fel d 1 and Can f 1 (pet allergens). Furthermore, we extracted the filters on month 6 and 12 and measured major allergens of cat and dog, Can f 1 and Fel d 1.

Clinical evaluation (lung function testing, cold air challenge, symptom score, medication, questionnaire on quality of life [published by Elizabeth Juniper]) took place on month 0, month 6 and 12.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Forced Expiratory Volume in one second (FEV1) after cold air challenge on month 0, 6 and 12.

Secondary outcome measures
1. Symptom score
2. Quality of life questionnaire
3. Cat and dog allergen exposure in bulk dust and filters
4. Eosinophil Cationic Protein (ECP) levels in serum as a marker of inflammation

Secondary outcomes were measured on month 0, 6 and 12.

Overall study start date
01/10/1999

Completion date
31/10/2000

Eligibility

Key inclusion criteria
1. Aged 6 to 18 years
2. Significant cat or dog allergen exposure greater than 500 ng/g in house dust
3. A doctor's diagnosis of asthma, sensitisation (serum Immunoglobulin E [IgE] to cat and/or dog)

Participant type(s)
Patient

Age group
Child

Lower age limit
6 Years

Upper age limit
18 Years

Sex
Not Specified

Target number of participants
36 enrolled, 3 participants had to be excluded due to bad compliance, 3 dropped out later. 30 finished the study.

Total final enrolment
36

Key exclusion criteria
1. Systemic corticosteroids
2. Mite allergy above 0.7 KU/L
3. Missing consent of parents

Date of first enrolment
01/10/1999

Date of final enrolment
31/10/2000

Locations

Countries of recruitment
Germany

Study participating centre
Charite Campus Virchow University Children's Hospital
Berlin
Germany
13353

Sponsor information

Organisation
Incen AG (Switzerland)

Sponsor details
Blumenfeldtrasse 15
Goldach
Switzerland
CH-9403
+41 (0)71 8440844
info@incen.com

Sponsor type
Industry

Website
http://www.incen.com

Funder(s)

Funder type
Industry

Funder Name
Incen AG (Switzerland) - provided filter systems

Funder Name
Charite - University Medicine Berlin (Germany) - provided funding for nurses, doctors, students

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		01/01/2009	12/04/2021	Yes	No