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A pilot proposal to determine the effect of the airsonett airshower on sleep quality

Submission date	Recruitment status	[ ] Prospectively registered
22/03/2011	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
25/03/2011	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
12/05/2017	Respiratory	[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
11/MRE00/6

Study information

Scientific Title

A single-blind placebo-controlled trial to determine the effect of the airsonett airshower on sleep quality

Study objectives
1. In adults with allergic rhinitis sensitised to dust mite, cat or dog and with significant rhinitis-related sleep disturbance (NRQLQ=3), treatment with nocturnal temperature-controlled laminar airflow (TLA) results in improved total symptom score compared to placebo device, on the second night of treatment.
2. In adults with allergic rhinitis sensitised to dust mite, cat or dog and with significant rhinitis-related sleep disturbance (NRQLQ=3), nocturnal TLA results in reduced nasal IL-5, reduced diurnal variation in peak nasal inspiratory flow, reduced nasal nitric oxide (NO), reduced modified NRQLQ score (i.e. scored over past 48 hours rather than 1 week), improved sleep parameters as measured by polysomnography and the Somnomat.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Scotland A Research Ethics Committee, 28/02/2011, ref: 11/MRE00/6

Primary study design
Interventional

Study design
Single-blind placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Allergic rhinitis

Interventions
1. Four nights of study two with placebo Protexo device and two with active Protexo device
2. Allerguard pillow protectors to be used on all four nights

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Total nasal symptom score (itching, sneezing, rhinorrhoea, congestion rated as none=0, mild=1, moderate=2, severe=3)

Key secondary outcome(s)
1. Arousal index as measured by polysomnography
2. Other polysomnography parameters
3. Spirometry
4. Exhaled NO, nasal NO as measured by NIOX MINO device

5. Peak nasal inspiratory flow
6. Nasal inflammometry nasal secretions collected bilaterally using filter paper strips (7x30 mm)
7. Somnomat
8. Visual analogue scale for sleepiness 100 mm scale from extremely sleepy (0 mm) to not sleepy at all (100 mm)
9. Visual analogue scale for sleep quality 100 mm scale from worst nights sleep ever (0 mm) to best nights sleep ever (100 mm)

Completion date
26/05/2011

Eligibility

Key inclusion criteria
1. Age 18-65
2. Doctor-diagnosed allergic rhinitis
3. Sensitised to house dust mite, cat or dog
4. Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire more than or equal to 3

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Key exclusion criteria
1. Current smoker
2. Moderate/severe asthma
3. Current medication which cannot be stopped and may affect allergic inflammation or sleep
4. Body mass index (BMI) > 30
5. Known sickle cell disease
6. Adenotonsillar hypertrophy
7. Current immunotherapy

Date of first enrolment
24/03/2011

Date of final enrolment

26/05/2011

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Imperial College London
London
United Kingdom
W2 1PG

Sponsor information

Organisation
Airsonett AB (Sweden)

Funder(s)

Funder type
University/education

Funder Name
Imperial College London (UK)

Alternative Name(s)
Imperial College of Science, Technology and Medicine, Imperial College London, UK, Imperial College London, London, England, Imperial College London in United Kingdom, imperialcollege, ICL

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration