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Temperature controlled airflow (air shower) treatment in children with severe skin allergy

Submission date
16/01/2015

Recruitment status
No longer recruiting

Registration date
14/03/2015

Overall study status
Ongoing

Last Edited
02/11/2023

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol
Background and study aims
Tiny particles in the air that cause allergies such as dust mite and pollen or those from cats and pollutants from traffic exhaust fumes can lead to health problems. Avoidance of these tiny particles can improve health. Unfortunately, complete avoidance of these particles inside the home is often not possible. In this study, we shall test a new treatment called Airsonett, for removing these particles in the air, on children.

Who can participate?
Children aged 2–16 years old with severe skin allergies

What does the study involve?
Airsonett will be installed in the rooms of participants, so that they are surrounded by clean and slightly cooler air while they are sleeping.

What are the possible benefits and risks of participating?
A benefit is the avoidance of particles in the air that cause allergies. Risks were not provided at the time of registration.

Where is the study run from?
Imperial College Health Care NHS Trust (UK)

When is the study starting and how long is it expected to run for?
From January 2015 to December 2025

Who is funding the study?
Imperial College Biomedical Research Centre (UK)

Who is the main contact?
Dr Claudia Gore

Contact information

Type(s)
Public

Contact name
Dr Claudia Gore

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Temperature controlled laminar airflow treatment in children with severe atopic eczema: a pilot study

Study objectives
Temperature controlled laminar airflow (TLA) treatment improves severe eczema in children, leading to reduced health care use, better sleep and quality of life

Ethics approval required
Old ethics approval format

Ethics approval(s)
Local research ethics committee (London-Fulham) number 14/LO/0130

Study design
Single centre open-label extended pilot study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
1. Severe atopic eczema, treatment resistant or dependent on potent topical/systemic therapy
2. Most participants will have multiple allergic comorbidities, such as allergic rhino conjunctivitis, asthma and food allergies

Interventions
1. A TLA device (Airsonett) will be installed for all participants
2. Airsonett is a European Union registered medical device and has been approved in the United Kingdom for use by consumers; it produces highly filtered clean air that is 0·5°C cooler than the rest of the air in the room; this cooler air surrounds individual while he or she is sleeping and filters the tiny particles and allergens in their breathing zone (i.e., the air a person would breathe in) during sleep
3. In the week before and after the installation of the TLA device, aeroallergen sampling will take place and a novel home sleep-study device will be in place to assess changes in sleep quality
4. Participants will have detailed clinical follow-up

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Not provided at time of registration

Primary outcome measure
Improvement in sleep and pruritus (SCORAD-C, visual analogue score)
Measured at 1 month, 3 months, 6 months, 12 months.

Secondary outcome measures
1. Reduction in Health Care Utilisation
2. Cost score combining medication requirement and unscheduled healthcare visits
3. Improvement in eczema related quality of life (validated questionnaires: CDQoL, FDI)
4. Change in allergen exposure during TLA use in home environment (particle counting, airsampling)
5. Improvement in rhinitis related quality of life. (Paed RQLQ)
6. Change in sleep quality as assessed by home sleep study (Sonomat)

All Outcomes measured at 1 month, 3 months, 6 months, 12 months.
Except:
1. Sonomat Outcome, measured at 3-4 days post treatment start.
2.Change in allergen exposure, measured at 3-4 days post treatment start.

Overall study start date
15/01/2015

Completion date
31/12/2025

Eligibility

Key inclusion criteria
1. Age 2–16 years old
2. Severe atopic eczema and evidence of sensitization to at least one perennial allergen (house dust mite, pets or mould
3. Consent to participate voluntarily and parental consent if participant is younger than 16 years old
4. Willing and able to comply with the study specific procedures; signed informed consent needed before any study procedure
5. Sufficient space to install the TLA device in the home

Participant type(s)
Patient

Age group
Child

Lower age limit
2 Years

Upper age limit
16 Years

Sex
Both

Target number of participants
15

Total final enrolment
15

Key exclusion criteria
Unwilling or unable to comply with the study protocol

Date of first enrolment
15/01/2015

Date of final enrolment
31/12/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Imperial College Health Care NHS Trust
London
United Kingdom
W2 1NY

Sponsor information

Organisation
Imperial College

Sponsor details
Regulatory Compliance Office
Room 510A
Level 5 Lab Block
Charing Cross Hospital
Fulham Palace Road
London
England
United Kingdom
W6 8RF

Sponsor type
University/education

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
University/education

Funder Name
Imperial College Biomedical Research Centre (UK)

Results and Publications

Publication and dissemination plan
Presentation at national/international meetings; publication in scientific journal; further plan to be confirmed later

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
Not provided at time of registration

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	01/05/2018	01/10/2019	Yes	No
HRA research summary			28/06/2023	No	No