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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
16/01/2015		Protocol		
Registration date	Overall study status	Statistical analysis plan		
14/03/2015	Ongoing	[X] Results		
<b>Last Edited</b> 02/11/2023	Condition category Skin and Connective Tissue Diseases	[] 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

Dept of Paediatric Allergy St Mary's Hospital Imperial College Healthcare NHS Trust Praed Street London United Kingdom W2 1NY

# 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  $0.5^{\circ}$ 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	<b>Details</b> results	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		01/05/2018	01/10/2019	Yes	No
HRA research summary			28/06/2023	No	No