

# A study to describe the clinical and biological characteristics of patients with suspected or known airways disease

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<b>Registration date</b> 24/05/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 17/11/2023	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

The aim of this study is to describe the clinical and biological characteristics of patients with suspected or known airways disease.

### Who can participate?

Patients aged over 18 years who are referred to the complex airways service at North Bristol NHS Trust

### What does the study involve?

As this study is an observational study it does not involve participants undertaking any extra visits, investigations, blood tests or medications which are not part of their usual standard care to manage their airways disease. This study will also act as a 'platform' study so the researchers will also ask each participant if they would like to be approached to take part in future studies based on the data collected.

### What are the possible benefits and risks of participating?

As the study is only documenting data that relates to a participant's standard care therefore the researchers do not expect any added risks or burdens. Participants will be contributing to the growing knowledge in this area and improving care for patients with airways disease.

### Where is the study run from?

Southmead Hospital (UK)

### When is the study starting and how long is it expected to run for?

October 2022 to June 2029

### Who is funding the study?

1. Bristol Biomedical Research Centre (UK)
2. The Southmead Hospital Charity Fund (UK)
3. AstraZeneca (UK)

Who is the main contact?

Dr Caitlin Morgan, [caitlin.morgan@nbt.nhs.uk](mailto:caitlin.morgan@nbt.nhs.uk)

## Contact information

### Type(s)

Public

### Contact name

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## Additional identifiers

### Clinical Trials Information System (CTIS)

Nil known

### Integrated Research Application System (IRAS)

321349

### ClinicalTrials.gov (NCT)

Nil known

**Protocol serial number**

IRAS 321349, CPMS 55429

## Study information

**Scientific Title**

BRistol Evaluation of novel Airways diagnostics, Therapies & Healthcare outcomEs

**Acronym**

BREATHE

**Study objectives**

Airways diseases have multiple phenotypes and by understanding the treatable and non-treatable traits of each phenotype, we will be able to improve clinical and patient-reported outcomes.

**Ethics approval required**

Ethics approval required

**Ethics approval(s)**

approved 12/05/2023, Westminster Research Ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 104 8283; westminster.rec@hra.nhs.uk), ref: 23/LO/0279

**Study design**

Single-centre longitudinal observational cohort study

**Primary study design**

Observational

**Study type(s)**

Other

**Health condition(s) or problem(s) studied**

Diagnosis and management of airways disease

**Interventions**

BREATHE is a single-centre, prospective longitudinal cohort study of patients who are referred to the Complex Airways Clinic at North Bristol NHS Trust (NBT). It is a platform which will include different sub-studies when they are developed in the future (with amendments reviewed by the sponsor and HRA at the time). BREATHE will record routinely collected clinical data at each stage of the multidisciplinary assessment, diagnosis and management of each patient from initial assessment until they are discharged by the service, or the study ends. The study will not include any additional investigations, questionnaires or patient visits which would not have been included as part of each patient's routine clinical management. The landscape of airway disease management will change over the next 5 years. As such BREATHE will incorporate an adaptive study design. As novel diagnostics and therapeutics emerge, it is anticipated that changes will be made to standard care which would necessitate changes to the data that is collected. If

substantial changes are made, they will be assessed for inclusion in the study and request further ethical approval if necessary. The BREATHE cohort is to be a source of potential subjects for future studies.

### **Intervention Type**

Other

### **Primary outcome(s)**

The clinical and biological characteristics of patients with suspected or known airways disease, described using standard care clinical data over a 5-year period

### **Key secondary outcome(s)**

1. Airways disease phenotypes and impact on disease outcomes assessed using standard care data collected over a 2-year period for each patient
2. Impact of the multidimensional clinical assessment on disease outcomes assessed by reviewing MDT outcomes over the 5-year study period
3. Response to treatment offered as part of the Complex Airways Service, assess by reviewing clinical and patient-reported outcomes over the 5-year study period
4. The prevalence of asthma mimics in this population, including inducible laryngeal obstruction (ILO), assessed by reviewing ILO diagnosis and clinical and patient-reported outcomes over a 2-year funded study period

### **Completion date**

01/06/2029

## **Eligibility**

### **Key inclusion criteria**

1. Participant is willing and able to give informed consent for participation in the study
2. Known or suspected airways disease

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

16 years

### **Sex**

All

### **Key exclusion criteria**

1. Participants who lack the capacity to consent for themselves
2. Aged below 16 years

**Date of first enrolment**

15/11/2023

**Date of final enrolment**

01/06/2028

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**North Bristol NHS Trust**

Southmead Hospital

Southmead Road

Westbury-on-trym

Bristol

United Kingdom

BS10 5NB

## **Sponsor information**

**Organisation**

North Bristol NHS Trust

**ROR**

<https://ror.org/036x6gt55>

## **Funder(s)**

**Funder type**

Charity

**Funder Name**

Southmead Hospital Charity

**Funder Name**

AstraZeneca

**Alternative Name(s)**

AstraZeneca PLC, Pearl Therapeutics, AZ

**Funding Body Type**

Government organisation

**Funding Body Subtype**

For-profit companies (industry)

**Location**

United Kingdom

**Funder Name**

NIHR Bristol Biomedical Research Centre

**Alternative Name(s)**

NIHR Biomedical Research Centre Bristol, National Institute for Health Research Bristol Biomedical Research Centre, NIHR Bristol BRC, Bristol BRC, Bristol Biomedical Research Centre

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Research institutes and centers

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The data-sharing plans for the current study are unknown and will be made available at a later date

**IPD sharing plan summary**

Data sharing statement to be made available at a later date

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Protocol file</a>	version 1.1	16/08/2023	19/10/2023	No	No