

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

Submission date 17/04/2023	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 24/05/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 17/11/2023	Condition category 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

Contact information

Type(s)

Public

Contact name

Dr Caitlin Morgan

ORCID ID

<https://orcid.org/0000-0001-7133-0195>

Contact details

Learning and Research Building

Southmead Hospital

Bristol

United Kingdom

BS10 5NB

+44 (0)7739708065

caitlin.morgan@nbt.nhs.uk

Type(s)

Principal investigator

Contact name

Dr James Dodd

ORCID ID

<https://orcid.org/0000-0003-4805-5759>

Contact details

Learning and Research Building

Southmead Hospital

Bristol

United Kingdom

BS10 5NB

+44 (0)1174147925

james.dodd@nbt.nhs.uk

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?
Protocol file	version 1.1	16/08/2023	19/10/2023	No	No