

# ABRS: The asthma breathing record study

<b>Submission date</b> 10/02/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 28/02/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/10/2024	<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

Asthma is a common lung condition that causes occasional breathing difficulties. People with more severe asthma suffer from frequent asthma attacks that require regular hospital admissions. These attacks are difficult to predict and can devastate the lives of patients. We need a new tool that can help to predict when an asthma attack is going to happen. This would help people recognise an attack earlier and allow treatment to be started sooner. We will study a new breathing monitor, to see whether it can detect asthma attacks.

The study tests a new device, called 'N-Tidal C', which uses a method that has the potential to predict when attacks are about to happen. We have found that people with asthma breathe out a gas, called carbon dioxide (CO<sub>2</sub>), in a different way to healthy people. The pattern of breathing out CO<sub>2</sub> (the waveform) changes further when patients are having an attack of their disease. If patients could monitor their CO<sub>2</sub>, they may recognise when their asthma is getting worse, and take earlier action to avoid attacks getting out of hand and going to hospital.

### Who can participate?

Persons aged 7 years or older with moderate or severe poorly controlled asthma.

### What does the study involve?

The participant will be asked to fill out questionnaires about their asthma, how bad it is and how it affects them. They will have standard tests to verify the severity of their asthma. They will then take the N-Tidal C device home and use it twice a day for a period of 6 months (or up to 12 months in the adult group). Each participant will have contact with the research team at follow up visits. Also twice a week they will respond to an automated telephone call or text message provided by Message Dynamics to report any attacks.

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

There might not be any direct benefit. The use of the device will help us work out whether it could help in the future, in predicting asthma attacks early and providing care and treatment as quickly as possible. This will hopefully keep more adults and children with asthma well and out of hospital for longer. Participants will not get any results or feedback from the device that is of any immediate use in their treatment. However the information the researchers get from this study will help us to develop the device, and to learn more about what happens to the breathing pattern before and at the time of an attack. An earlier version of the device has already been tested in a previous study by participants with breathing problems over a 6 month period. There

were no difficulties or side effects reported from using the device. The researchers do not expect there to be any side effects with this device over the full study period of 6-12 months.

Where is the study run from?  
Queen Alexandra Hospital (UK)

When is the study starting and how long is it expected to run for?  
January 2020 to July 2021

Who is funding the study?  
NIHR Central Commissioning Facility (CCF) (UK)

Who is the main contact?  
Prof. Anoop Chauhan  
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## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**Clinical Trials Information System (CTIS)**  
Nil known

**Integrated Research Application System (IRAS)**  
262873

**ClinicalTrials.gov (NCT)**  
NCT04504838

**Protocol serial number**  
CPMS 43221, IRAS 262873, Grant Code II-LA-1117-20002

## Study information

**Scientific Title**

A longitudinal, observational study to explore the Tidal Breathing Carbon Dioxide (TBCO<sub>2</sub>) waveform, measured using the N-Tidal C device, in asthma

**Acronym**

ABRS

**Study objectives**

The N Tidal C device will be able to predict when an asthma attack is going to happen.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Approved 04/09/2019, South Central Berkshire Research Ethics Committee (Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, UK; +44 (0)207148049; nrescommittee.southcentral-berkshire@nhs.net), ref: 19/SC/0420

**Study design**

Interventional non-randomized study

**Primary study design**

Interventional

**Study type(s)**

Prevention

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

Asthma

**Interventions**

The ABRS study will be carried out in 3 different cohorts; adults at Queen Alexandra Hospital, Adults in Primary care in Oxford, and Children at Queen Alexandra Hospital. The aim is to gain information about the changes in the CO<sub>2</sub> waveform before, during and after an asthma attack.

Design and patient flow:

All eligible participants will perform informed consent, and will then have baseline characteristics recorded, along with past medical history and demographical information. We will perform breathing tests, including spirometry and FeNO. They will each be given a peak flow meter and their baseline peak flow will be recorded. Each participant will be issued with a personalized asthma action plan. They will be given an N-Tidal C device and shown how to use it and maintain it. Each participant,(or their parent) will sign up to the Message Dynamics automated call system.

Twice a week, participants will be asked to record their symptoms and asthma control through the Message Dynamics system either via telephone call or text. If they respond positively to any of the questions they will receive a call back from the study team. In Portsmouth adults only, the participants will be invited back for an 'exacerbation visit' at one point when they are exacerbating during the study. At this time they will receive a doctor review, and we will measure FeNO and a history of their exacerbation. If necessary we will make treatment changes. A letter will be sent to the GP. All participants will be encouraged to seek usual care for an asthma attack, whether that be through the GP, Urgent care centre or Emergency Department.

**Intervention Type**

Device

**Phase**

Phase IV

**Drug/device/biological/vaccine name(s)**

N-Tidal C

**Primary outcome(s)**

TBCO2 waveform parameters before an asthma exacerbation measured using the N Tidal C Device

**Key secondary outcome(s)**

1. Asthma - severity measured by BTS Stage 2-5 (adult cohort -baseline, 3 months, 6 months, 9 months and 12 months) (paediatric cohort - baseline, 3 months, 6 months)
2. Disease Control - measured by asthma control questionnaire (adult cohort -baseline, 3 months, 6 months, 9 months and 12 months) (paediatric cohort - baseline, 3 months, 6 months)
3. Quality of life - measured by Asthma quality of life questionnaire (adult cohort -baseline, 3 months, 6 months, 9 months and 12 months) (paediatric cohort - baseline, 3 months, 6 months)
4. Lung Function – measured by spirometry (adult cohort -baseline, 3 months, 6 months, 9 months and 12 months) (paediatric cohort - baseline, 3 months, 6 months)
5. Airway Inflammation measured by fractional exhaled Nitric Oxide (FeNO) (adult cohort - baseline, 3 months, 6 months, 9 months and 12 months) (paediatric cohort - baseline, 3 months, 6 months)
6. Airway resistance – measured by Airway Oscillometry (adult cohort – baseline and 12 months, paediatric cohort baseline and 6 months)

**Completion date**

31/12/2022

**Eligibility****Key inclusion criteria**

1. Male or Female, aged  $\geq 7$  years
2. Confirmed clinician diagnosis of asthma by examination of medical records, and based on accepted national and/or international criteria e.g. BTS/SIGN, or GINA
3. Moderate or Severe asthma (defined as BTS stage 2-5)
4. Poorly controlled asthma (defined as an ACQ score of  $\geq 1$ )
5. Exacerbation prone asthma (defined as at least 1 asthma exacerbation requiring oral corticosteroid treatment in the last 12 months)
6. Providing written informed consent, or parental/guardian consent and participant assent in the case of a child

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

7 years

**Sex**

All

**Total final enrolment**

124

**Key exclusion criteria**

1. Inability to understand or comply with study procedures and/or inability to give fully informed consent
2. Known other lung, chest wall, neuromuscular, cardiac or other comorbidity or abnormality that would affect spirometry and/or other measures of lung function or TBCO<sub>2</sub> measurements (including Breathing Pattern Disorder or Chronic Obstructive Pulmonary Disease)
3. Smokers (current or ex-smokers) with a > 10 pack-year history
4. In the opinion of the clinical investigator, the participant would have difficulty completing the study procedures consistently (for example, difficulty holding the device, or long periods of absence/travel) throughout the study period

**Date of first enrolment**

31/01/2020

**Date of final enrolment**

30/04/2022

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

Queen Alexandra Hospital

Southwick Hill Road

Portsmouth

United Kingdom

PO6 3LY

**Sponsor information**

**Organisation**

Cambridge Respiratory Innovations Limited

**Funder(s)****Funder type**

Government

**Funder Name**

NIHR Central Commissioning Facility (CCF)

**Funder Name**

National Institute for Health Research (NIHR) (UK)

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

**Results and Publications****Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository. The de-identified 'raw data' will be held on Portsmouth Hospitals NHS trust servers. The type of data that will be available after de-identification will be text, tables, figures. The data will be available at the beginning and ending 12 months after the article publication. Data will be available to researchers who provide a sound proposal – these should be directed to [Anoop.chauhan@porthosp.nhs.uk](mailto:Anoop.chauhan@porthosp.nhs.uk) for access and requestors will be to sign a data sharing agreement.

**IPD sharing plan summary**

Stored in non-publicly available repository

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[HRA research summary](#)

28/06/2023 No

No

[Participant information sheet](#)

Participant information sheet

11/11/2025

11/11/2025 No

Yes