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ABRS: The asthma breathing record study

Submission date 10/02/2020	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 28/02/2020	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/10/2024	**Condition category** Respiratory	[_] Individual participant data [X] 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_2), in a different way to healthy people. The pattern of breathing out CO_2 (the waveform) changes further when patients are having an attack of their disease. If patients could monitor their CO_2, 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
anoop.chauhan@porthosp.nhs.uk

Contact information

Type(s)
Scientific

Contact name
Prof Anoop Chauhan

Contact details
Portsmouth Hospitals NHS Trust
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY
+44 (0)2392286000
anoop.chauhan@porthosp.nhs.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
262873

ClinicalTrials.gov number
NCT04504838

Secondary identifying numbers
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 (TBCO2) 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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 CO2 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 measure
TBCO2 waveform parameters before an asthma exacerbation measured using the N Tidal C Device

Secondary outcome measures
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)

Overall study start date
03/12/2018

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Male or Female, aged > = 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 > = 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

Age group
Adult

Lower age limit
7 Years

Sex
Both

Target number of participants
Planned Sample Size: 140; UK Sample Size: 140

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 TBCO2 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
England

United Kingdom

Study participating centre
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Cambridge Respiratory Innovations Limited

Sponsor details
The Grange
20 Market Street
Swavesey
Cambridge
United Kingdom
CB24 4QG
+44 (0)1954230793
john.foord@criltd.co.uk

Sponsor type
Industry

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

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
31/12/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publically 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 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?
HRA research summary			28/06/2023	No	No