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Measuring changes in FeNO using the second generation Nobreath® device before and after medication for persons with asthma and observing whether FeNO results are consistent when taken by different people

Submission date 04/09/2020	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol [ ] Statistical analysis plan [ ] Results [ ] Individual participant data [ ] Record updated in last year
Registration date 04/09/2020	**Overall study status** Completed	
Last Edited 11/01/2022	**Condition category** Respiratory	

Plain English summary of protocol

Background and study aims
Exhaled nitric oxide (FeNO) is widely known as a 'breath biomarker' for airway inflammation. This means that a nitric oxide sensor can detect the levels of FeNO from an individual. This allows medical practitioners to assess a patient's airway inflammation to support diagnosis and management of airway diseases such as asthma. The aim of this study is to see whether Bedfont® Scientific's FeNO analyser (NoBreath® V2) provides repeatable measurements when used by different practitioners. This study will also seek to monitor the change in FeNO levels between visits separated by 14 days.

Who can participate?
Healthy volunteers or patients with a history or current diagnosis of asthma, aged 7 or above

What does the study involve?
The study is likely to last 2-3 weeks with two visits. For the first visit, the researchers will take measurements of FeNO and lung function and then repeat these at the second visit. At each visit they will also ask the participant to complete an asthma control questionnaire if the participant currently has a diagnosis of asthma. For those participants who have a diagnosis of asthma the researchers will also assess the participant's inhaler technique at each visit.

What were the possible risks and benefits of participating?
Possible benefits of taking part in the study include identifying possible uncontrolled asthma so that appropriate steps to control asthma can be referred and taken by the relevant organisations. The study is deemed to be a low-risk study. The device used in the study is currently sold in the UK and in many other countries. The medical device currently holds a CE mark meaning it meets EU performance and safety standards. The procedures are not invasive and only require breath samples to be taken. Other procedures such as lung function

measurements and questionnaires (and FeNO scores) are already recommended procedures to assist with asthma diagnosis in the UK, and are widely acknowledged and adopted around the world. The aim is to make the FeNO devices more accessible around the world and aid in the support of FeNO being used as a tool to aid to diagnose and manage asthma. There is a low chance that performing the lung function measurement may trigger an asthma response in participants with asthma. The labs will conform to all health and safety protocols to ensure chances of coming in contact with COVID-19 virus are as minimised as possible. This will involve the researcher and participant being asked to wear Personal Protective Equipment (PPE) where appropriate. This includes at a minimum, masks for the duration participants are on site. In addition, the lab spaces and equipment will be sanitised between participants. For each assessment participants will use single-use disposable mouthpieces that include filters.

Where is the study run from?
Bedfont® Scientific Ltd (UK)

When did the study start and how long is it expected to run for?
February 2020 to October 2020

Who is funding the study?
Bedfont® Scientific Ltd (UK)

Who is the main contact?
Hannah Vince-Drew
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
138.326

Study information

Scientific Title
A method comparison study comparing intra- and inter-user reproducibility of FeNO measurement using the NObreath® V2

Study objectives
1. To demonstrate a significant and clinically meaningful decrease in FeNO as a biomarker of inflammation, to evaluate an asthma subject's clinical response to approximately 14 days of inhaled and, in some participants, oral steroid therapy and to evaluate the intra-operator and inter-operator variability measured by the NObreath® v2.
2. To demonstrate that the change in FeNO after corticosteroid therapy is accompanied by improvement in spirometry, asthma symptoms, and asthma control questionnaire (ACQ) scores.
3. To assess the repeatability and variability of FeNO measured by the NO breath between practitioners on the same day and separated by 14 days.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 17/08/2020, School of Sport & Exercise Sciences Research Ethics and Advisory Group (REAG), (University of Kent at Medway, Medway Building, Central Ave, Gillingham, Kent, ME4 4AG, UK; +44 (0)1227 827833; ssesethics@kent.ac.uk), ref: 58_2019_20
Approved 12/05/2020, ethics committee platforma Brazil (Rua Dr. Almeida Lima, 1.134 - 2o andar - sala 207, Brazil; +55 (0)11 2790 4658; cep@anhembi.br), ref: not applicable

Study design
Open-label randomized multi-group and multi-centre study in adult and paediatric populations

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Diagnostic

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

Health condition(s) or problem(s) studied
Asthma in adult and paediatric populations

Interventions
On the first visit, participants will complete FeNO analysis with three practitioners in a randomised order, spirometry, complete an asthma control questionnaire (ACQ) and have inhaler technique assessed (asthma participants only). Participants' respiratory health will be analysed using measurements from FeNO, spirometry and ACQ. Those whose respiratory function is deemed healthy or well-controlled asthma will have no intervention. Those who are deemed to have respiratory function suggestive of uncontrolled asthma (FeNO >25 adults ppb; >20 ppb children) will have inhaler technique training and be advised to visit their general practitioner for adjustment of prevention therapy. The second visit will repeat all the assessments from visit 1. Comparisons will be made between measurements taken by practitioners and between visits.

Intervention Type
Device

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
FeNO analyser device second-generation NOBreath

Primary outcome measure
1. The repeatability and variability of FeNO measured by the second generation NObreath® by three practitioners with two repeats at baseline and after 14 days (±3 days) after therapeutic agents are administered
2. Asthma control measured using asthma control questionnaire (ACQ) at baseline and after 14 days (±3 days) after therapeutic agents are administered
3. FEV1/FVC measured with a spirometry device at baseline and after 14 days (±3 days) after therapeutic agents are administered

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/02/2020

Completion date
30/10/2020

Eligibility

Key inclusion criteria
1. Aged 7 years or above
2. If on allergy immunotherapy treatment this must be a stable regimen during the study
3. Be capable of producing valid FeNO measurements via the NObreath®
4. Be capable of performing spirometry in accordance with ATS/ERS criteria

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
200 participants (100 asthma; 100 healthy)

Total final enrolment
186

Key exclusion criteria
1. Hospitalisation related to asthma in the past 6 months
2. Use of oral corticosteroid in the 4 weeks prior to visit 1
3. Use of biological therapies e.g. mepolizumab in 12 weeks prior to visit 1
4. Other respiratory diseases e.g. COPD or cystic fibrosis
5. Known intolerance to inhaled corticosteroids or salbutamol
6. Cardiovascular conditions:
6.1. Coronary artery disease
6.2. High blood pressure
6.3. Heart failure
6.4. Diagnosed abnormality of heart rhythm
7. A smoking history of >10 packs per year
8. Pregnant

Date of first enrolment
30/07/2020

Date of final enrolment
23/10/2020

Locations

Countries of recruitment
Brazil

England

United Kingdom

Study participating centre
Bedfont Scientific Ltd
Station Yard
Station Road
Harrietsham

Maidstone
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ME17 1JA

Study participating centre
Kent University
Medway Building
Central Ave
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United Kingdom
ME4 4AG

Study participating centre
Medway Asthma Self-Help (MASH)
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ME7 2YY

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Study participating centre
Private Clinic Elisa Coutinho
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Sponsor information

Organisation

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Bedfont® Scientific Ltd

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. The protocol can be made available on request on a case by case basis.

Intention to publish date
30/10/2022

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