

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 04/09/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 11/01/2022	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

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
Hannah@bedfont.com

Contact information

Type(s)
Public

Contact name
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hannah@bedfont.com

Additional identifiers

Protocol serial number
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 plataforma Brazil (Rua Dr. Almeida Lima, 1.134 - 2o andar - sala 207, Brazil; +55 (0)11 2790 4658; cep@anhembibr.com.br), ref: not applicable

Study design

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

Primary study design

Interventional

Study type(s)

Diagnostic

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(s)

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

Key secondary outcome(s)

There are no secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Mixed

Sex

All

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

United Kingdom

England

Brazil

Study participating centre

Bedfont Scientific Ltd

Station Yard
Station Road
Harrietsham
Maidstone
United Kingdom
ME17 1JA

Study participating centre

Kent University

Medway Building
Central Ave
Gillingham
United Kingdom
ME4 4AG

Study participating centre

Medway Asthma Self-Help (MASH)

131 Watling St
Gillingham
United Kingdom
ME7 2YY

Study participating centre**Private office/clinic Dr Claudio Frison**

Rua Paraibuna
811 -13º andar - sala 1302 Ed. Office 811
São José dos Campos
Sao Paulo
Brazil
SP, 12245-020

Study participating centre**Private Clinic Elisa Coutinho**

Rua Paraibuna 811 Sala 1302
São José dos Campos
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Brazil
SP, 12245-020

Sponsor information

Organisation

Bedfont® Scientific Ltd

Funder(s)

Funder type

Industry

Funder Name

Bedfont® Scientific Ltd

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